

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE**

SHELBY COUNTY, TENNESSEE,)	Case No.
)	
Plaintiff,)	JURY TRIAL DEMANDED
)	
v.)	
)	
PURDUE PHARMA, L.P.;)	
PURDUE PHARMA, INC.;)	
THE PURDUE FREDERICK COMPANY)	
INC.;)	
MALLINCKRODT PLC;)	
MALLINCKRODT LLC;)	
ENDO HEALTH SOLUTIONS INC.;)	
ENDO PHARMACEUTICALS INC.;)	
TEVA PHARMACEUTICAL INDUSTRIES)	
LTD.;)	
TEVA PHARMACEUTICALS USA, INC.;)	
CEPHALON, INC.;)	
JOHNSON & JOHNSON;)	
JANSSEN PHARMACEUTICALS, INC.;)	
ORTHO-MCNEIL-JANSSEN)	
PHARMACEUTICALS, INC. n/k/a JANSSEN)	
PHARMACEUTICALS, INC.;)	
JANSSEN PHARMACEUTICA, INC. n/k/a)	
JANSSEN PHARMACEUTICALS, INC.;)	
NORAMCO, INC.;)	
AMERISOURCEBERGEN DRUG)	
CORPORATION;)	
CARDINAL HEALTH, INC.; and)	
MCKESSON CORPORATION,)	
)	
Defendants.)	

COMPLAINT

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Plaintiff Shelby County, Tennessee (“Plaintiff”) brings this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., Mallinckrodt plc, Mallinckrodt LLC, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc. (“Producer Defendants”), AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation (“Distributor Defendants”) (collectively “Defendants”). Based upon personal knowledge, information, belief, and investigation of counsel, Shelby County alleges:

INTRODUCTION

1. To say that the United States is awash in opioids is a monumental understatement. Despite accounting for a mere five percent of the world’s total population, the United States consumes approximately 80 percent of the entire world’s opioids, including 99 percent of the world’s hydrocodone. Even more staggering are the number of opioid-related deaths: each day, more than 90 people in the United States will die from an opioid overdose, on average. The unprecedented rate of opioid overdoses has actually caused overall death rates in the United States to rise, reversing a century of year-to-year decline in mortality statistics.

2. In Tennessee, the opioid crisis has reached epidemic proportions. In 2015, there were more opioid prescriptions than people in Tennessee. Tennessee paramedics increasingly spend time responding to overdoses, and Tennessee coroners are running out of room to store bodies. According to the Tennessee Department of Health, 1,631 Tennesseans died from drug

overdoses in 2016.¹ This sobering total, the highest number of overdose deaths recorded in state history, represents a 477 percent increase from the 342 overdose deaths recorded among Tennesseans in 1999.

3. The opioid epidemic did not appear overnight. It is the result of a concerted effort among the Producer Defendants, along with other opioid manufacturers, to mislead doctors and the public about the need for, and addictive nature of, opioid drugs. The Producer Defendants spent years engaged in a fraudulent scheme to push their wares into a market of unsuspecting doctors and patients. When it became clear that entire regions of the country were being devastated by addiction to these drugs, the Producer Defendants turned a blind eye to the problems and collected millions of dollars in ill-gotten profits.

4. The Producer Defendants falsely and misleadingly: (a) downplayed the serious risk of addiction; (b) promoted the concept of “pseudoaddiction” and thus advocated that the signs of addiction should be treated with more opioids; (c) exaggerated the effectiveness of screening tools in preventing addiction; (d) claimed that opioid dependency and withdrawal are easily managed; (e) denied the risks of higher opioid dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. The Producer Defendants also falsely touted the benefits of long-term opioid use, including the purported ability of opioids to improve function and quality of life, even though there was no reliable scientific evidence to support the Producer Defendants’ claims.

5. The Producer Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians that Defendants

¹ Tennessee Drug Overdose Dashboard. Available at: <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

recruited for their support of Defendants' marketing messages.

6. The Producer Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Producer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, medical conferences and seminars, and scientific articles. Working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and convince them of quite the opposite, that the compassionate treatment of pain *required* opioids.

7. The Producer Defendants knew that their misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.

8. Opioid producing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

9. The Distributor Defendants are major distributors of controlled substances, and

like the Producer Defendants, the Distributor Defendants were aware of a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied. The Producer Defendants and the Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed in Shelby County. However, both the Producer Defendants and the Distributor Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to increasing abuse, addiction, and overdose rates in Shelby County.

10. The Distributor Defendants' violations have already led to fines elsewhere. McKesson Corporation, the largest prescription drug wholesaler company in the United States, agreed on January 17, 2017, to pay a \$150 million fine to the federal government for such misconduct.² In December 2016, Cardinal Health, Inc. reached a \$34 million settlement with the federal government regarding similar conduct.³ One month later, Cardinal Health, Inc. also reached a \$20 million settlement with the State of West Virginia.⁴ AmerisourceBergen Drug Corporation has also recently agreed to pay West Virginia \$16 million for similar violations.⁵

11. Defendants' scheme has met with tremendous success, if measured by profit. In 2010 alone, opioids generated \$11 billion in revenue for drug companies.⁶ Of that amount, \$3.1

² 2017 Administrative Memorandum of Agreement (DOJ, DEA and McKesson). Available at: <https://www.justice.gov/opa/press-release/file/928476/download>.

³ Press Release, *United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act*, DOJ, U.S. Attorney's Office – Middle District of Florida. Available at: <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

⁴ Eric Eyre, *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail, January 9, 2017. Available at: <http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits>.

⁵ *Id.*

⁶ Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune.com, Nov. 9, 2011. Available at: <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

billion went to Purdue for its OxyContin sales.⁷ Opioids are now among the most prescribed class of drugs, and the United States' opioid painkiller market is worth an estimated \$10 billion annually.⁸ According to *Fortune* magazine, the Distributor Defendants are each among the top 15 companies in the 2017 *Fortune* 500: McKesson, No. 5, with \$192 billion in total revenue; AmerisourceBergen, No. 11, with \$122 billion in total revenue; and Cardinal Health, No. 15, with \$122 billion in total revenue.⁹ Additionally, the Sackler family, which owns Purdue – a privately held company – was included on Forbes 2015 list of America's Richest Families, coming in at a stunning \$14 billion.¹⁰

12. The rising numbers of persons addicted to opioids have led to increased health care costs and a dramatic increase in social problems, including drug abuse and diversion¹¹ and the commission of criminal acts to obtain opioids throughout the United States, including Shelby County. Public health and safety throughout the United States, including Shelby County, has been significantly and negatively affected due to widespread inappropriate use of the drugs manufactured and distributed by Defendants.

13. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff Shelby County incurred considerable expenses each year in its efforts to combat the

⁷ *Id.*

⁸ Ariana Eun Jung Cha, *The drug industry's answer to opioid addiction: More pills*, The Washington Post, Oct. 16, 2016. Available at: https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.42e0328ca459.

⁹ Erika Fry, *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson Is Feeling the Pain*, Fortune.com, June 13, 2017. Available at: <http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/>.

¹⁰ Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes, July 1, 2015. Available at: <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4b11d5d375e0>.

¹¹ As described below, diversion is a term used to describe the redistribution of prescription drugs for illegal uses.

opioid epidemic created by Defendants' conduct. Plaintiff Shelby County has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, lost productivity, and lost revenue.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this action under 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

15. This Court also has subject-matter jurisdiction over this action under 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds \$75,000, exclusive of interest and costs.

16. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Tennessee, purposefully directed their actions toward Tennessee, consensually submitted to the jurisdiction of Tennessee when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Tennessee necessary to constitutionally permit the Court to exercise jurisdiction.

17. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District. Moreover, Plaintiff Shelby County is located in this District, and a substantial part of property that is the subject of this action is situated in this District.

PARTIES

I. Shelby County

18. Shelby County, Tennessee is located within the Western Division of the Western District of Tennessee. According to U.S. Census Bureau statistics, it is estimated that Shelby County's total population was 934,603 in July 2016. Shelby County is Tennessee's largest county both in terms of population and geographic area. Its county seat is Memphis.

19. The current Mayor of Shelby County is Mark H. Luttrell, Jr.

20. Mayor Luttrell, Jr. has the authority under the laws of the State of Tennessee to bring this lawsuit on behalf of Shelby County.

II. Producer Defendants

A. Purdue

21. Defendant Purdue Pharma L.P., is a limited partnership organized under the laws of Delaware. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. are referred to collectively as "Purdue."

22. In Tennessee and nationally, Purdue is engaged in the manufacture, promotion, and distribution of opioids, including: (a) OxyContin (OxyContin hydrochloride extended release), a Schedule II opioid agonist¹² tablet first approved in 1995 and marketed by Purdue for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." OxyContin was indicated,

¹² An opioid *agonist* is a drug that activates certain opioid receptors in the brain. By contrast, an *antagonist* relieves pain by blocking the receptor.

or legally approved, for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”; (b) MS OxyContin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

23. OxyContin is Purdue’s largest-selling opioid. Since 2009, Purdue’s national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up approximately four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

24. Purdue transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Purdue hires employees to service the Tennessee market. For example, Purdue recently posted online that it was seeking a District Business Manager and a Territory Business Manager to operate out of Knoxville, Tennessee. Purdue also directs advertising and informational materials to impact Tennessee physicians and potential users of Purdue products.

25. PURDUE PHARMA L.P. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE 19808. PURDUE PHARMA INC. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 80 State Street, Albany, NY 12207. THE PURDUE FREDERICK COMPANY INC. can be served through its registered agent: Corporation Service Company, 80 State Street, Albany, NY 12207.

B. Mallinckrodt

26. Defendant Mallinckrodt plc is an Irish public limited company headquartered in

Staines-upon-Thames, United Kingdom, and maintains a U.S. headquarters in St. Louis, Missouri. Defendant Mallinckrodt LLC is a Delaware limited liability company with its principal place of business in St. Louis, Missouri. Mallinckrodt plc and Mallinckrodt LLC are referred to collectively as “Mallinckrodt.”

27. In Tennessee and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of hydrocodone, Roxicodone, Oxycodone and hydromorphone among other drugs. Mallinckrodt transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Mallinckrodt hires employees to service the Tennessee market. For example, Mallinckrodt has recently advertised for the position of Regional Reimbursement Manager, Neurology, Tennessee/Ohio, to operate out of Cleveland, Ohio and Knoxville, Tennessee. Mallinckrodt also directs advertising and informational materials to impact Tennessee physicians and potential users of Mallinckrodt products. Upon information and belief, Mallinckrodt also maintains an office located at 1835 Nonconah Blvd. # 153, Memphis, Tennessee, which is located in Shelby County.

28. MALLINCKRODT can be served through its registered agent in the United States: Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

C. Endo

29. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

30. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc., and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred

to collectively as “Endo.”

31. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the U.S. and Tennessee. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

32. Endo transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Endo hires employees to service the Tennessee market. For example, Endo recently posted online that it was seeking a District Sales Manager, Pain Management, to operate out of Memphis, Tennessee. Endo also directs advertising and informational materials to impact Tennessee physicians and potential users of Endo products. Upon information and belief, Endo also operates an office at 1910 Danielson Place, Memphis, Tennessee, which is located in Shelby County.

33. ENDO HEALTH SOLUTIONS can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. ENDO PHARMACEUTICALS INC. can be served through its registered agent: The Corporation Trust Company, Corporate Trust Center, 1209 Orange Street, Wilmington, DE 19801.

D. Cephalon and Associated Companies

34. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation with its headquarters at 5 Basel St. in Petach Tikva, Israel 49131.

35. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, in Frazer, Pennsylvania 19454.

36. Teva Pharmaceutical Industries Ltd. acquired Cephalon, Inc. in October 2011, and Cephalon, Inc. became a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

37. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business at 1090 Horsham Rd in North Wales, Pennsylvania 19454 and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

38. Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as “Cephalon.”

39. In Tennessee and nationally, Cephalon is engaged in the manufacture, promotion, and distribution of hydrocodone and oxycodone among other drugs. Cephalon transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Cephalon also directs advertising and information materials to impact Tennessee physicians and potential users of Cephalon products.

40. CEPHALON, INC. can be served through its registered agent: Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, DE 19810. TEVA PHARMACEUTICAL INDUSTRIES, LTD can be served through the Hague Convention Authorities. TEVA PHARMACEUTICALS USA, INC. can be served through its registered agent: Corporate Creations Network, Inc, 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, DE 19810.

E. Johnson & Johnson, Janssen, and Associated Companies

41. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey 08933.

42. Defendant Janssen Pharmaceuticals, Inc. (“Janssen Pharmaceuticals”) is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harborton Rd, in Titusville, New Jersey 08560, and is a wholly owned subsidiary of Johnson & Johnson. It was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Ortho-McNeil-Janssen”), which in turn was formerly known as Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”).

43. Defendant Ortho-McNeil-Janssen is or was a Pennsylvania corporation with a principal place of business in New Jersey.

44. Defendant Janssen Pharmaceutica is or was a Pennsylvania corporation with a principal place of business in New Jersey.

45. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware. Noramco was a wholly owned subsidiary of Johnson & Johnson until July 2016, when Johnson & Johnson divested it. Noramco is or had been part of Johnson & Johnson’s opioid processing by making active pharmaceutical ingredients (“APIs”) for opioid painkillers.

46. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals’ stock. Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals’ drugs, and Janssen Pharmaceuticals’ profits inure to Johnson & Johnson’s benefit.

47. Johnson & Johnson, Janssen Pharmaceuticals, Noramco, Ortho- McNeil-Janssen, and Janssen Pharmaceutica are referred to collectively as “Janssen.” Janssen is or has been in the business of manufacturing, selling, promoting, and/or distributing brand name and generic opioids throughout the United States, including in Tennessee.

48. JOHNSON & JOHNSON can be served through its registered agent: Johnson &

Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933. JANSSEN PHARMACUETICALS, INC., formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc. can be served through its registered agent: CT Corporation System, 600 N. 2nd Street, Suite 401, Harrisburg, PA 17101. NORAMCO, INC. can be served through its registered agent the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801

49. Purdue, Endo, Mallinckrodt, Cephalon, and Janssen are referred to collectively as the “Producer Defendants.”

III. Distributor Defendants

A. AmerisourceBergen

50. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business located at 1300 Morris Drive in Chesterbrook, Pennsylvania 19087. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

51. According to its 2016 Annual Report, AmerisourceBergen is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”

52. AmerisourceBergen distributes opioids that are produced by Producer Defendants throughout Tennessee, specifically in Shelby County.

53. AMERISOURCEBERGEN can be served through its registered agent, the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

B. Cardinal Health

54. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal Health generated revenues of \$121.5 billion. Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant times, distributed opioids nationwide.

55. Cardinal Health distributes opioids that are manufactured by Producer Defendants throughout Tennessee, specifically in Shelby County.

56. CARDINAL HEALTH can be served through its registered agent, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219

C. McKesson

57. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with its principal place of business located in San Francisco, California.

58. McKesson is the largest pharmaceutical distributor in the United States, as well as North America at whole. McKesson delivers approximately one-third of all pharmaceuticals used in North America.

59. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion.

60. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in

healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”

61. According to the 2017 Annual Report, McKesson “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

62. McKesson has more than 40,000 customers nationally.

63. McKesson distributes opioids that are manufactured by Producer Defendants throughout Tennessee, specifically in Shelby County.

64. MCKESSON can be served through its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

65. Collectively, McKesson, AmerisourceBergen, and Cardinal Health (the “Distributor Defendants”) account for 85 percent of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

FACTUAL ALLEGATIONS

I. Opioids have never been proven appropriate for the treatment of chronic pain and other non-acute medical problems

66. Producer Defendants played a central role in the creation of the United States, Tennessee, and Shelby County’s opioid crises, by fraudulently marketing opioids for chronic pain and other non-acute ailments. The scientific consensus that opioids are dangerous, highly addictive, and inappropriate for chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries – existed in the mid-1990s and has never been challenged in any meaningful scientific way.

67. The National Safety Council, a not for profit organization chartered by Congress

to improve public health, has published a summary of research titled “Evidence for the Efficacy of Pain Medications.”¹³ The National Safety Council report concludes that “[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice.”¹⁴

68. Multiple researchers have found that “no evidence exists to support long term use – longer than four months – of opioids to treat chronic pain.”¹⁵

69. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women’s Hospital, Harvard Medical School, concluded that “[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found.”¹⁶

70. The same review found that “[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group.”¹⁷

71. Dr. Kissin further concluded that “[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective.”¹⁸

II. Opioids carry a high risk of addiction, serious medical problems, and death

72. Opioids have severe side effects, including: gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine

¹³ Donald Teater, Nat’l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) [hereinafter *Evidence for Efficacy*].

¹⁴ *Id.* at 6 (emphasis added).

¹⁵ *Id.* (citing multiple publications).

¹⁶ Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), available at <https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-pain> bspunproven-ef-peer-reviewed-article-JPR.

¹⁷ *Id.*

¹⁸ *Id.*

abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.¹⁹

73. Research based on actual patient interviews has found that, **among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime opioid dependence and 25.8% met the criteria for current opioid dependence.**²⁰

74. Dr. Wilson M. Compton, the Director of the National Institute of Drug Abuse and Deputy Director of the National Institute of Health, co-authored a 2006 study that concluded: “[t]hough the use of opioid analgesics for the treatment of acute pain appears to be generally benign, **long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction.**”²¹

75. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two-thirds of patients who took opioids daily for ninety days were still taking opioids five years later.²²

76. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.²³

77. Dr. Mitchell H. Katz, current director of the Los Angeles County Health Agency, has described how patients with nonmalignant conditions can end up as drug addicts because of

¹⁹ Donald Teater, Nat’l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) [hereinafter *Side Effects*] (summarizing side effect data).

²⁰ Joseph A. Boscarino, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>.

²¹ Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat’l Inst. on Drug Abuse 103, 103-07 (2006).

²² Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).

²³ *Evidence for Efficacy at 5* (citing Radcliff et al., *Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?*, 38(14) The Spine J. E849, E849-60 (2013)).

the prescribing of opioids:

A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol].... For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. ...You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they “don’t run out before the next visit.” Before you know it, the patient is on a high dose of an opioid, and you are unsure whether you have actually helped them. **What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose.**²⁴

III. The origins of the current opioid epidemic can be traced back to the Producer Defendants’ decades-long fraudulent marketing campaign

78. The United States’ and Tennessee’s opioid crisis is no accident: it is the result of a conspiracy between the Producer Defendants and other opioid manufacturers to fraudulently convince physicians that opioids carried a low risk of addiction and were therefore appropriate for non-acute problems like chronic pain.

79. The Producer Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. The Producer Defendants infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioid use was evidence-based

²⁴ Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010).

medicine when, in fact, it was not. Huge profits resulted from these efforts, as did the present addiction, abuse, diversion, and overdose crisis.

A. The Producer Defendants use “unbranded” marketing to evade laws and regulations

80. Drug companies’ promotional activity can be unbranded or branded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. Unbranded advertising is not regulated by the FDA. The Producer Defendants evade the FDA’s extensive regulatory framework governing branded communications by using unbranded advertising.

81. The federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits the sale in interstate commerce of drugs that are “misbranded.” A drug is “misbranded” if it lacks “adequate directions for use” or if the label is false or misleading “in any particular.”

82. The Producer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unregulated, unbranded marketing materials that generally promoted opioid use, but did not name a specific opioid. Through these unbranded materials, the Producer Defendants presented information and instructions concerning opioids in general that were false and misleading.

83. The Producer Defendants also acted through third parties so that they could give the false appearance that their messages reflected independent views. Later, the Producer Defendants cited to these sources as “independent” corroboration of their own statements. Further, as one physician adviser to the Producer Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not “push back” at displaying materials from non-profits such as American Pain Foundation (“APF”), in their offices, as they would with drug company materials.

84. As part of their marketing scheme, the Producer Defendants spread their deceptive messages through the following unbranded materials: (i) so-called “key opinion leaders” (“KOLs”) (i.e., physicians who influence their peers’ medical practice, including but not limited to prescribing behavior), who wrote favorable journal articles and delivered supportive Continuing Medical Education (“CME”) programs; (ii) treatment guidelines; and (iii) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations (“Front Groups”), which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

85. The Producer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that the Producer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, the Producer Defendants exercised control over their deceptive messages and acted in concert with these third parties to promote the use of opioids for the treatment of chronic pain.

86. The unbranded marketing materials that the Producer Defendants assisted in creating and distributing did not disclose the true risks of addiction, abuse, misuse, and overdose, and affirmatively denied or minimized those risks.

B. The Producer Defendants paid so-called KOLs and sponsored speakers’ bureaus to disseminate false and misleading messaging

87. The Producer Defendants cultivated a select circle of doctors chosen and sponsored by the Producer Defendants because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the hub of the Producer Defendants’ promotional efforts, presenting what typically appears to be unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors

wrote, consulted, edited, and loaned their names to books and articles, all while giving speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain, and they have served on the boards of purportedly independent pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. The Producer Defendants were able to exert control of each of these modalities through their KOLs.

88. In return for their pro-opioid advocacy, the Producer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

89. The payments to KOLs all too frequently come in the form of consulting and speaking fees. The total payments from the Producer Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows that even small amounts of money can have large effects on doctors' prescribing practices.²⁵

90. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession ("IMAP"), speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor.²⁶ As the IMAP publication explains: "Speakers' bureaus may lead to the dissemination of false or biased information. Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may

²⁵ Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016). Available at: <http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/>.

²⁶ IMAP, *Speakers' Bureaus: Best Practices for Academic Medical Centers* (Oct. 10, 2013). Available at: http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf.

influence the attitudes or judgment of the presenter.”²⁷

91. The Producer Defendants cited and promoted their KOLs and studies or articles written by their KOLs to broaden the chronic opioid therapy market. By contrast, the Producer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of using chronic opioid therapy.

92. The Producer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. Producer Defendants also kept close tabs on the content of the materials published by these KOLs.

93. In their promotion of using opioids to treat chronic pain, the Producer Defendants’ KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth, but they continued to publish their misstatements to benefit themselves and Producer Defendants.

C. The Producer Defendants funded Front Groups that published and disseminated false and misleading marketing materials

94. The Producer Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Producer Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

95. **Federation of State Medical Boards:** The Federation of State Medical Boards (“FSMB”) is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Defendants

²⁷ *Id.*

Purdue, Cephalon, and Endo have provided substantial funding to the FSMB.

96. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for \$100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to **700,000** practicing doctors.

97. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

- Pain management is integral to good medical practice and for all patients;
- *Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;*
- *Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.*

Four key factors contribute to the ongoing problem of under-treated pain: (1)

Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities; (3) *Misunderstanding of addiction and dependence*; and (4) Lack of

understanding of regulatory policies and processes.²⁸

98. While it acknowledges the risk of “abuse and diversion” (with little attention to addiction), the guide purports to offer “professional guidelines” that will “easily and efficiently” allow physicians to manage that risk and “minimize the potential for [such] abuse.”²⁹ Indeed, it states that even for those patients assessed to have risk of substance abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated,” just that physicians should use additional care in prescribing.

99. The guide further warns physicians to “[b]e aware of the distinction between pseudoaddiction and addiction” and teaches that behaviors such as “[r]equesting [drugs] by name,” “[d]emanding or manipulative behavior,” “[o]btaining opioid drugs from more than one physician” and “[h]oarding opioids,” which are, in fact, signs of genuine addiction, are all really just signs of “pseudoaddiction.”³⁰ It defines “Physical Dependence” as an acceptable result of opioid therapy not to be equated with addiction and states that while “[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications,” there could be other acceptable reasons for non-adherence.³¹ The guide, sponsored by the Producer Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

100. In 2012, Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

²⁸ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide* 8-9 (Waterford Life Sciences 2007).

²⁹ *Id.* at 9.

³⁰ *Id.* at 62.

³¹ *Id.*

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, *it's critical to remember that the problem of unrelieved pain remains as urgent as ever.*³²

101. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.”³³

102. In another guide by Fishman, he continues to downplay the risk of addiction: “*I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical copper’ and an addict.*”³⁴ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

103. The heightened focus on the under-treatment of pain was a concept designed by the Producer Defendants to sell opioids. *The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain.*³⁵ Among the drafters of this policy was Dr. J. David Haddox (“Haddox”), who coined the term “pseudoaddiction,” which wholly lacked scientific evidence but quickly became a common way for the Producer Defendants and their allies to promote the use of opioids, even to patients displaying addiction symptoms. Haddox later became a Purdue Vice President.

104. In 2012 and again in 2017, each of the guides, as well as their sources of funding,

³² Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

³³ *Id.* at 11.

³⁴ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

³⁵ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1. Available at: <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

became the subjects of Senate investigations.

105. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning the latter's investigation into the abuse and misuse of opioids.³⁶ While the FSMB letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "Studies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" has been distributed in each of the 50 states and the District of Columbia.

106. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 through the present. Included in the payments received are the following payments: Defendant Purdue paid the FSMB a total of \$822,400.06 from 2001 to 2008; Defendant Endo paid the FSMB a total of \$371,620.00 from 2007 to 2009 and 2011 to 2012; Defendant Cephalon paid the FSMB a total of \$180,000.00 from 2007 to 2008 and 2011; and Defendant Mallinckrodt paid the FSMB \$100,000.00 in 2011.

107. The letter also disclosed payments of \$40,000 by Endo and \$50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing" and disclosed that 42,366 copies of "Responsible Opioid Prescribing" were distributed in Michigan alone.

108. **The Joint Commission:** The Joint Commission is an organization that establishes

³⁶ June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

standards for treatment and accredits healthcare organizations in the United States. The Producer Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what the Producer Defendants coined the “under-treatment of pain,” referenced pain as the “fifth vital sign” (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors’ concerns about addiction “inaccurate and exaggerated.”

109. In 2000, the Joint Commission printed a book for doctors to purchase as part of required continuing education seminars, which cited studies claiming “*there is no evidence that addiction is a significant issue when persons are given opioids for pain control.*” The book was sponsored by Defendant Purdue.

110. In 2001, the Joint Commission and the National Pharmaceutical Council – founded in 1953 and currently supported by the nation’s major research-based companies, including Johnson & Johnson, Purdue, and Cephalon, among others – collaborated to issue a 101-page monograph titled “Pain: Current understanding of assessment, management, and treatments.” The monograph states falsely that beliefs about opioids being addictive are “erroneous”:

Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.

b. Etiology, issues, and concerns

Many medications produce tolerance and physical dependence, and some (e.g., opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most

experts agree that *patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low.* A recent study of opioid analgesic use revealed “low and stable” abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .

*Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and Heidrich, Zenz et al.), surveys indicate that clinicians often overestimate this risk.*³⁷

111. The Producer Defendants’ infiltration and influence over the Joint Commission’s standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission’s guidelines.³⁸ Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.³⁹

112. **American Pain Foundation:** The American Pain Foundation (“APF”), headquartered in Baltimore, Maryland, described itself as the nation’s largest organization for pain patients. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen, and Cephalon. APF received more than \$10

³⁷ *Pain: Current Understanding of Assessment, Management, and Treatments* 16-17 (Dec. 2001). Available at: <http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf> .

³⁸ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It’s So Hard to Stop*, at 119 (Johns Hopkins University Press 2016).

³⁹ *Id.* at 42.

million in funding from the Producer Defendants and other opioid manufacturers from 2007 through 2012, when it abruptly shut down days after the U.S. Senate Committee on Finance (“Senate Finance Committee”) launched an investigation into APF’s promotion of prescription opioids.

113. The APF’s guides for patients, journalists, and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.

114. For example, in 2001, APF published “Treatment Options: A Guide for People Living with Pain.” The guide, which was produced due to support from companies including Defendants Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because “[c]alling *opioid analgesics ‘narcotics’ reinforces myths and misunderstandings* as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines”;
- stated that “[o]pioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma;” and
- opined that “[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction.”

115. The guide included blurbs from Dr. Russell Portenoy (“Portenoy”), who is quoted as saying “[t]his is a very good resource for the pain patient,” and Fishman, who is quoted as saying, “[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A ‘must have’ for every physician’s waiting room.”

116. In 2003, APF published a newsletter titled “Best of . . . The Pain Community

News” that purported to clarify any confusion over addiction and opioids and emphasized the “tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction.”

117. In 2009, Defendant Endo sponsored APF’s publication and distribution of “Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families” (“Exit Wounds”), a book described as “the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb.” It also purported to “offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system.”

118. Among other false statements, Exit Wounds reported: “Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.*” Endo, through APF, thus distributed false information with the purpose of providing veterans false information they could use to “self-advocat[e]” for opioids while omitting a discussion of the risks associated with opioid use.

119. The APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. In a brochure available on painknowledge.org titled “Pain: Opioid

Facts,” the NIPC misled that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted” and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.

120. In or around 2011, the APF published the “Policymaker’s Guide,” sponsored by Purdue, which dispelled the notion that “strong pain medication leads to addiction” by characterizing it as a “*common misconception*[]”:

Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed.⁴⁰

121. The guide describes “pain in America” as “an evolving public health crisis” and characterizes concerns about opioid addiction as misconceptions: “Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . *Misconceptions about opioid addiction.*”⁴¹ It even characterizes as a “*myth*” that “[c]hildren can easily become addicted to pain medications.”⁴² The guide further asserts, falsely, that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients.

122. In December 2011, the *Washington Post* reported on ProPublica’s investigation of the APF, which detailed APF’s close ties to drug makers:

[T]he pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation’s

⁴⁰ *A Policymaker’s Guide to Understanding Pain & Its Management*, American Pain Foundation, at 5. Available at: <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited Jan. 2, 2018).

⁴¹ *Id.* at 6.

⁴² *Id.* at 40

largest advocacy group for pain patients. *Its message: The risk of addiction is overblown, and the drugs are underused.*

What the nonprofit organization doesn't highlight is the money behind that message.

The foundation collected nearly 90 percent of its \$5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions, an examination by ProPublica found.⁴³

123. **American Academy of Pain Medicine and American Pain Society:** The Producer Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) for decades.

124. In 1997, the AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The chairman of the committee that issued the statement, Haddox, was, at the time, a paid speaker for Purdue. Haddox was later hired as Purdue’s vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM’s website. AAPM’s corporate council includes Purdue, Depomed, Cephalon and other pharmaceutical companies. AAPM’s past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine (“Fine”) (2011) and Lynn R. Webster (“Webster”) (2013), all of whose connections to the opioid manufacturers are well-documented.

125. At or about the same time, the APS introduced the “pain as the 5th vital sign” campaign, followed soon thereafter by the U.S. Department of Veterans Affairs adopting that

⁴³ Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011). Available at: https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.b0c95f6870f4.

campaign as part of their national pain management strategy.

126. AAPM and APS issued guidelines in 2009 (“2009 Guidelines”) that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from at least one, if not more, of Defendants Janssen, Cephalon, Endo, and Purdue.

127. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.⁴⁴ The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids: they were reprinted in the journal *Pain*, have been cited hundreds of times in academic literature, and still remain available online. The Producer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

128. **Opioid Manufacturers Funnel Millions of Dollars to Advocacy Groups that Promote Opioid Use.** On February 13, 2018, Senator Claire McCaskill, released a report showing that Purdue and other producers funneled over \$10 million to 14 advocacy groups and affiliated doctors who took “industry friendly positions,” which included issuing medical guidelines promoting opioids for chronic pain, lobbying to defeat or include exceptions to state limits on opioid prescribing, and criticizing prescribing guidelines from the U.S. Centers for Disease Control and Prevention.⁴⁵ The Report states as that these industry-funded entities and affiliated physicians:

⁴⁴ Roger Chou, *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non- Cancer Pain*, 10(2) J. Pain 113 (Feb. 2009). Available at: [http://www.jpain.org/article/S1526-5900\(08\)00831-6/pdf](http://www.jpain.org/article/S1526-5900(08)00831-6/pdf).

⁴⁵ <http://www.wjhl.com/news/national/opioid-makers-gave-10m-to-advocacy-groups-amid-epidemic-1/971172541>.

[o]ften echoed and amplified messages favorable to increased opioid use – and ultimately the financial interest of opioid manufacturers. These groups have issued guidelines and policy minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over-prescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain – the first national standards for prescription opioids and a key federal response to the ongoing epidemic.

The fact that these same manufacturers provided millions of dollars to the group described [in this report] suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals this way, the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.⁴⁶

IV. The Producer Defendants' Specific Unlawful Conduct

129. The Producer Defendants, through their own marketing efforts and publications, and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Shelby County. These promotional messages were intended to and encouraged patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

130. Doctors are the gatekeepers for all prescription drugs. Thus, not surprisingly, the Producer Defendants focused the bulk of their marketing efforts – as well as their multi-million dollar budgets – on the professional medical community. Opioids are highly regulated controlled substances, which creates barriers to prescribing. In light of those barriers, the Producer Defendants knew that doctors would not prescribe opioids to patients with common chronic pain

⁴⁶ Fueling an Epidemic, Report Two: *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Group*, U.S. Homeland Security & Governmental Affairs Committee, Ranking Member's Office, <https://www.publicintegrity.org/2018/02/12/21568/021218-mccaskill-report>.

complaints unless those doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, the Producer Defendants did not disclose to prescribers, patients, or the public that evidence to support their promotional claims was inconclusive, non-existent, or unavailable. Rather, each Producer Defendant disseminated misleading and unsupported messages that caused the target audience to believe that those messages were corroborated by scientific evidence. As a result, doctors, including those in Shelby County and the surrounding areas, prescribed opioids long term to treat chronic pain – a treatment plan most doctors would have never considered prior to the Producer Defendants’ campaign.

131. The Producer Defendants’ marketing campaigns have materially impacted doctors’ prescribing behavior.⁴⁷ Doctors rely on drug companies like the Producer Defendants to provide them with truthful information about the risks and benefits of their products. They are also influenced by their patients’ requests for particular drugs.

132. The Producer Defendants spent millions of dollars to market their drugs to prescribers and patients while meticulously tracking their respective returns on that investment. A 2015 survey published by the American Medical Association (“AMA”) shows how effective this campaign was. Even though nine general practitioners in ten surveyed reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for

⁴⁷ See, e.g., Manchanda, P. & Chintagunta, P.K. Marketing Letters (2004) 15: 129; Larken, Ian et al., “Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children,” *Health Affairs* 33, no.6 (2014):1014-1023 (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). See also Van Zee, Art, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy.” *American Journal of Public Health* 99.2 (2009): 221–227. *PMC* (noting an increase of OxyContin prescriptions from 670,000 annually in 1997 to about 6.2 million in 2002 and an approximate doubling of Purdue’s internal sales force from 1996 to 2000).

chronic non-cancer pain.⁴⁸

133. These results are a direct result of the Producer Defendants' fraudulent marketing campaign, which included:

- misrepresenting the truth about how opioids lead to addiction;
- misrepresenting that opioids improve patient function;
- misrepresenting that addiction risk can be managed;
- deceiving doctors, patients, and payors through misleading terms like "pseudoaddiction";
- falsely claiming that opioid withdrawal is simply managed;
- misrepresenting that increased doses pose no significant additional risks; and
- falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

134. Underlying each of the Producer Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was the Producer Defendants' collective effort to hide the fact that no adequate and well-controlled studies of long-term opioid use exist.⁴⁹

A. Purdue

i. Purdue set out to end medical providers' long-standing fear of prescribing opioids

135. As stated by Tennessee Department of Health Commissioner Dreyzehner, "**in the**

⁴⁸ Hwang, Catherine S. et al., "Prescription Drug Abuse A National Survey of Primary Care Physicians.," *JAMA Intern Med.* 2015;175(2):302–304.

⁴⁹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

1990's, MD's started prescribing opioids in large volume to treat [nonmalignant] pain which has caused an opioid addiction problem.”⁵⁰ Commissioner of the Tennessee Department of Mental Health Douglas Varney, while speaking at a meeting of the Governor's Opioid Abuse Working Group, similarly concluded that **“[b]asically we are dealing with the fallout from the medical profession overprescribing opioids.”**

136. Up until the mid-1990s, physicians prescribed opioids primarily to cancer patients and persons recovering from surgery. Fearful of the addictive qualities of opioids, physicians would not generally prescribe them for long term chronic pain. As detailed in a 2015 review of the development of the opioid crisis, **“[p]rior to the introduction of OxyContin [by Purdue in 1995], many physicians were reluctant to prescribe OPRs [opioid pain relievers] on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence.”**⁵¹

137. Purdue's own research confirmed the mid-1990s consensus of medical providers regarding the dangers of opioids. According to the Agreed Statement of Facts signed by Purdue in connection with a 2007 guilty plea to federal criminal charges for misbranding OxyContin: **“During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain... ‘[t]he biggest negative of [OxyContin] was the abuse potential.’”**⁵²

138. As Purdue prepared to introduce OxyContin to the U.S. market, including Tennessee and Shelby County, it carefully evaluated physicians' concerns about the risks of

⁵⁰ *Working Group Report* at attachment 2.

⁵¹ Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).

⁵² Information as to Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc., No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-2 at ¶19 (alteration in original).

addiction associated with opioids and embarked on a highly successful, fraudulent campaign to convince physicians that OxyContin created minimal risk of addiction. As Purdue's efforts to defraud prescribers and the public demonstrated success in the form of rapid increases in opioid prescription rates, Mallinckrodt, Endo, Cephalon, Janssen, and other opioid producers joined Purdue in its fraudulent scheme.

ii. Purdue's aggressive marketing of OxyContin fueled ever-increasing and excessive demand for the drug

139. From the outset of its nationwide OxyContin marketing campaign, Purdue "aggressively" promoted the drug to physicians both inside and outside of Tennessee for non-cancer pain conditions that can be caused by arthritis, injuries, and chronic diseases.⁵³ Essential to this marketing strategy was Purdue's claim, later conceded to be fraudulent, that OxyContin rarely gave rise to addiction. Purdue went so far as to downplay the risk of addiction as likely in "less than one percent of patients."⁵⁴

140. Purdue's promotion of OxyContin for the treatment of non-cancer-related pain contributed to a "nearly tenfold" increase in OxyContin prescriptions for non-cancer-related pain, from approximately 670,000 prescriptions in 1997 to approximately 6.2 million prescriptions in 2002.⁵⁵

141. Purdue's marketing for OxyContin was bolstered by the bold claim that the drug was "the first and only 12-hour OxyContin pain medicine."⁵⁶ In a 1996 press release, Purdue

⁵³ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 222 (2009) [hereinafter *Van Zee*] (quoting Purdue's 1999 OxyContin Marketing Plan); *see also* U.S. Gov't Accounting Office, Report to Cong. Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 17 (2003) [hereinafter *OxyContin Abuse and Diversion*].

⁵⁴ *OxyContin Abuse and Diversion*, at 28.

⁵⁵ *Id.* at 18.

⁵⁶ Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain (May 31, 1996), *available at*

touted: “Unlike short-acting pain medications, which must be taken every 3 to 6 hours – often on an ‘as needed’ basis – OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night.”⁵⁷ That same press release included a “Background” section, which proclaimed that the “fear of addiction” to opioids was “exaggerated” and “largely unfounded.”⁵⁸

142. When it introduced OxyContin, Purdue had no meaningful evidence that supported its core claim that the drug’s addiction risk was minimal. It later admitted that this claim was fraudulent.⁵⁹

143. Purdue also had extensive evidence that its “12-hour relief” claims were false. This distinction was critical because patients who could not get 12-hour relief would often supplement their dosage, thereby increasing their risk of addiction.⁶⁰

144. Even before OxyContin went on the market, Purdue’s clinical trials showed many patients were not getting 12 hours of relief from a single dose. The first clinical study of OxyContin – which was designed and paid for by Purdue and overseen by Purdue scientists – occurred in 1989 and involved women recuperating from abdominal and gynecological surgeries at two hospitals in Puerto Rico. In that study, 90 women were given a single dose of OxyContin while other patients were given short-acting painkillers or placebos. More than a third of women given OxyContin started complaining of pain after just eight hours, and about half required more

<https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf>; *see also* Minutes from the OxyContin Launch Team Meeting (Mar. 31, 1995), *available at* <http://documents.latimes.com/oxycontin-launch-1995/>.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Clay Duda, *On the Front Lines of Knoxville’s Battle Against Opiate Addiction*, [knoxmercury.com](http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/), June 1, 2016, <http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/>.

⁶⁰ Harriet Ryan et al., ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, [latimes.com](http://www.latimes.com/projects/oxycontin-part1/), May 5, 2016, <http://www.latimes.com/projects/oxycontin-part1/>.

medication before the 12-hour mark.⁶¹

145. The results of the 1989 study were not unique. Dr. Daniel Brookoff, a Tennessee pain specialist whom Purdue selected to field-test OxyContin, ran into similar issues. In a 1995 clinical study completed as part of the Food and Drug Administration (“FDA”) approval process, Dr. Brookoff eventually moved 8 of 15 chronic pain patients to 8-hour dosing because they were not getting adequate relief taking the drug twice a day.⁶²

146. Purdue nevertheless launched an extensive campaign to market and promote the drug using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists, to prescribe OxyContin as an initial treatment for non-cancer pain.⁶³ This campaign was nationwide and directed at medical providers and potential consumers in Tennessee, among other states.

147. Utilizing marketing data, Purdue and its sales representatives pushed the false narrative that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than traditional, shorter-acting painkillers like Percocet or Vicodin.⁶⁴

148. To this end, Purdue used a series of deceptive videos and journal advertisements. For example, in 1998, Purdue distributed 15,000 copies of an OxyContin marketing video to physicians without submitting it to the FDA for review, as required under the Federal Food Drug and Cosmetic Act (“FD&C Act”).⁶⁵ In the Purdue video, entitled *I Got My Life Back: Patients in Pain Tell Their Story*, a physician “**stated that opioid analgesics have been shown to cause**

⁶¹ *Id.* (citing original documents from the study).

⁶² *Id.*

⁶³ OxyContin Abuse and Diversion at 16-24.

⁶⁴ Press Release, U.S. Attorney’s Office W.D. Va., *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin: Will Pay Over \$600 Million* (May 10, 2007), available at <https://health.mil/Reference-Center/Publications/2007/05/10/The-Purdue-Frederick-Company-Inc-and-Top-Executives-Plead-Guilty>. [hereinafter WV Press Release].

⁶⁵ OxyContin Abuse and Diversion at 27.

addiction in less than 1 percent of patients.”⁶⁶ That statement, according to the FDA, “has not been substantiated.”⁶⁷

149. In 2000, Purdue submitted a different promotional video to the FDA, this one entitled *I Got My Life Back: A Two Year Follow up of Patients in Pain*.⁶⁸ **The FDA found that Purdue’s video “appeared to make unsubstantiated claims regarding OxyContin’s effects on patients’ quality of life and ability to perform daily activities and minimized the risks associated with the drug.”⁶⁹** Ignoring the FDA’s concerns, Purdue distributed 12,000 copies of the videos to physicians.⁷⁰

150. Purdue also employed false or misleading medical journal advertisements that, as determined by the FDA, violated the FD&C Act. Notably, in January 2003, the FDA issued a stern warning letter to Purdue in response to two ads the company ran in the *Journal of the American Medical Association*, a prestigious publication distributed to physicians in Tennessee and throughout the United States:

Your journal advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective. Specifically, your journal advertisements fail to present in the body of the advertisements any information from the boxed warning in the approved product labeling (PI) for OxyContin regarding the potentially fatal risks associated with the use of OxyContin and the abuse liability of OxyContin, which is a Schedule II controlled substance, and make unsubstantiated efficacy claims promoting the use of OxyContin for pain relief. Your journal advertisements also understate the minimal safety information that is presented. Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements

⁶⁶ *Id.* at 28.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. **The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use, is especially egregious and alarming in its potential impact on the public health.**⁷¹

151. The message that the FDA deemed “egregious and alarming” – that OxyContin posed little risk of addiction and was thus appropriate for chronic non-cancer pain – was critical to Purdue’s sales and central to Purdue’s marketing efforts directed at prescribing physicians in Tennessee and throughout the United States. Purdue aggressively sought to influence physicians’ prescribing habits by inviting them to all-expenses-paid conferences. From 1996 to 2000, Purdue conducted more than 40 national pain management and speaker training conferences at resorts in Florida and Arizona.⁷² Before that practice was discontinued, more than 5,000 physicians, pharmacists, and nurse practitioners from Tennessee and elsewhere attended Purdue’s conferences, where they were recruited and trained for Purdue’s national speaker bureau.⁷³

152. On information and belief, Purdue sent annual “Dear Healthcare Provider” letters to Tennessee HCPs who prescribed opioids and enclosed copies of the *Providing Relief, Preventing Abuse* which Purdue authored, and which falsely pushed the concept of

⁷¹ Letter from Thomas W. Abrams, FDA, Dir. of Drug Mktg. Adver. And Comm’n, to Michael Friedman, Exec. Dir. Purdue Pharma, L.P. (Jan. 17, 2003), *available at* <http://wayback.archive-it.org/7993/20170112065652/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/UCM168946.pdf>.

⁷² OxyContin Abuse and Diversion at 22.

⁷³ *Id.*

pseudoaddiction.

153. On information and belief, Purdue widely disseminated *Providing Relief, Preventing Abuse* in Tennessee. Purdue sent the brochure in a letter form to the following number of health care providers in Tennessee in each of the years indicated: 1,984 in 2007; 1,424 in 2008; 1,130 in 2009; 952 in 2010; 808 in 2011; 799 in 2012; 1,055 in 2013; 956 in 2014; 715 in 2015; and 458 in 2016. Purdue distributed at least 10,281 copies of *Providing Relief, Preventing Abuse* by mail to providers in Tennessee.

154. On information and belief, Purdue's sales representatives also distributed and referred to the document in sales calls for its branded products. Purdue provided over 7,000 copies of *Providing Relief, Preventing Abuse* to Tennessee sales representatives and district managers to distribute in person.

155. Beginning in 1996, Purdue hired 318 sales representatives to implement its OxyContin marketing campaign.⁷⁴ By 2000, the number of sales representatives directly employed by Purdue had risen to 562, and Purdue added a Hospital Specialty Division which employed another 109 sales representatives.⁷⁵ At that time, the 671 Purdue sales representatives had a total physician call list of approximately 33,400 to 44,500 physicians.⁷⁶

156. Purdue had a lucrative bonus system that incentivized its sales representatives to increase sales of OxyContin to the highest volume prescribers of its opioid products, which it termed "super core" and "core" prescribers, in their respective territories. On information and belief, these prescribers were also more likely to be the most concerning relative to abuse and diversion of its opioid products. In 2001, in addition to the average sales representative's annual salary of \$55,000, annual bonuses averaged \$71,500, with a range of \$15,000 to nearly

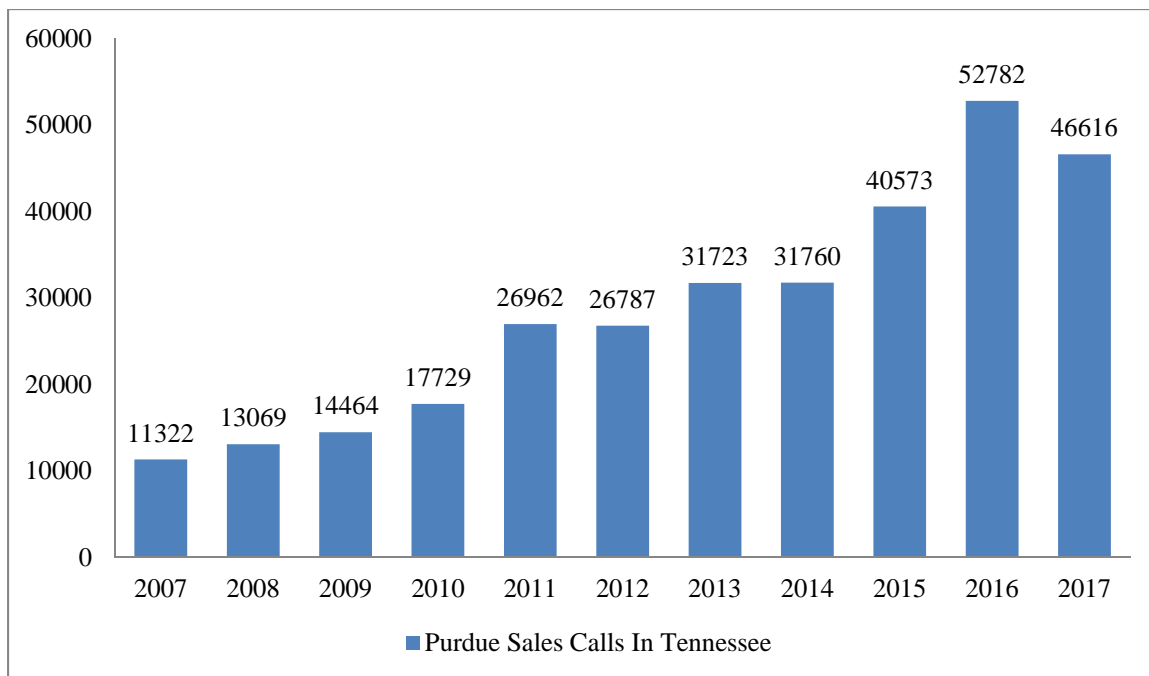
⁷⁴ *Id.*

⁷⁵ *Id.* at 19-20.

⁷⁶ *Id.* at 20.

\$240,000.⁷⁷ Purdue paid approximately \$40 million in bonuses tied to OxyContin sales in 2001.⁷⁸

157. On information and belief, Purdue's Tennessee sales representatives engaged in approximately 300,000 sales calls to Tennessee health care providers between May 7, 2007 and December 2017 – meaning that Purdue's sales representatives averaged *well over 100 sales calls to Tennessee providers per day* to promote its opioid products. Notably, Purdue increased its primary marketing tool in recent years in Tennessee even after receiving civil investigative demands and subpoenas from Tennessee and other state Attorneys General, being sued in litigation across the country, and as the devastating effects of the opioid epidemic became better known. Purdue increased the volume of sales calls dramatically in Tennessee over the last 10 years – particularly after the reformulation of OxyContin. The number of sales calls by Purdue sales representatives in Tennessee steadily increased from 11,322 in 2007 to a high of 52,782 in 2016, as shown in the chart below:



⁷⁷ *Id.*

⁷⁸ *Id.*

158. Purdue also entered into a co-promotion agreement with Abbott Laboratories (“Abbott”), through which Abbott provided an additional 300 sales representatives per year from 1996 through 2002.⁷⁹ The sales representatives from the two companies closely coordinated their efforts, met regularly to strategize, and shared marketing materials.⁸⁰ Internal Abbott and Purdue memos, as well as sales documents and marketing materials, show that Abbott sales representatives were instructed to downplay the threat of addiction with OxyContin and make other claims to doctors that had no scientific basis.⁸¹ For example, in one internal Abbott memo, which listed ideas to help sales personnel increase OxyContin’s share of pain-pill prescriptions written by orthopedic surgeons, Abbott told its sales representatives to highlight the “less abuse/addiction potential” of the drug, which could be taken just twice a day because of its time-release formulation.⁸²

159. The more Abbott generated in OxyContin sales, the higher the reward for the company. Under the agreement with Purdue, Abbott received 25 percent of all net sales, up to \$10 million, for prescriptions written by doctors its sales reps called on, and 30 percent of sales above \$10 million.⁸³ Accordingly, similar to Purdue, Abbott heavily incentivized its sales staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers.⁸⁴

160. One of the “critical foundations” of Purdue and Abbott’s marketing for OxyContin was the use of sophisticated marketing data to influence physicians’ prescribing

⁷⁹ *Id.* at 19-20.

⁸⁰ David Armstrong, *Secret trove reveals bold ‘crusade’ to make OxyContin a blockbuster*, STAT News, September 22, 2106.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

habits.⁸⁵ By compiling prescriber profiles on individual physicians, the co-promoters were able to identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.⁸⁶ Purdue and Abbott then targeted the highest, and in some cases least discriminate, prescribers of opioids across the country.⁸⁷

161. Purdue and Abbott spent hundreds of millions of dollars promoting OxyContin through their respective sales forces because they understand that their representatives' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face "detailing" has the highest influence on intent to prescribe.⁸⁸ Purdue and Abbott could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more OxyContin. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.⁸⁹ Over the life of the co-promotional agreement, Purdue paid Abbott nearly 500 million dollars.⁹⁰

162. As part of its direct marketing campaign, Purdue distributed several types of

⁸⁵ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 222 (2009) [hereinafter *Van Zee*].

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in 34% decline in on-label use of promoted drugs); *see also* Van Zee at 222 (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

⁸⁹ David Armstrong, *Secret trove reveals bold 'crusade' to make OxyContin a blockbuster*, STAT News, September 22, 2106.

⁹⁰ *Id.*

branded promotional items to health care professionals.⁹¹ Among the items were OxyContin fishing hats, stuffed plush toys, music compact discs (entitled “Get in the Swing With OxyContin”), and pens containing a pullout conversion chart showing physicians how to calculate the dosage to convert a patient to OxyContin from other opioid pain relievers.⁹² **According to the U.S. Drug Enforcement Agency (“DEA”), the “use of such branded promotional items for a Schedule II opioid [was] unprecedented... and indicates Purdue’s aggressive, excessive, and inappropriate marketing of their product, OxyContin.”**⁹³

163. Akin to practices employed by street drug dealers, Purdue also gave away its addictive product to first-time users. “For the first time in marketing any of its products, Purdue used a patient starter coupon program for OxyContin to provide patients with a free limited-time prescription.”⁹⁴ Under this program, Purdue’s sales representatives distributed coupons to physicians who, in turn, decided whether to offer one to a patient, and then the patient could redeem a free prescription through a participating pharmacy. Approximately 34,000 coupons had been redeemed nationally when the program was terminated following the July 2001 OxyContin label change.

164. In conjunction with its direct marketing efforts, Purdue began an innovative indirect-marketing campaign for OxyContin. Because FDA regulations prohibit direct-to-consumer advertising of narcotics, Purdue decided to concentrate on “nonbranded education,” which would market the concept of pain relief to consumers. To this end, in 1997, the company launched the “Partners Against Pain” website available to consumers in Tennessee and

⁹¹ OxyContin Abuse and Diversion at 25.

⁹² *Id.*

⁹³ *Id.* at 56.

⁹⁴ *Id.* at 23.

throughout the United States.⁹⁵ Through a variety of articles, studies, and polls, the “Partners Against Pain” website “promoted three ideas to doctors and patients: that pain was much more widespread than had previously been thought; that it was treatable; and that in many cases it could, and should, be treated with opioids.”⁹⁶

165. Purdue also paid third parties to promote its messages in an effort to give its marketing claims a perception of scientific legitimacy. To this end, as explained in a 2015 history of the opioid crisis, “Purdue provided financial support to the [APS], the [AAPM], the [FSMB], pain patient groups, and other organizations. In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs [opioids].”⁹⁷

166. “To overcome what they claimed to be ‘opiophobia,’ physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with ‘physical dependence.’ They described addiction as rare and completely distinct from so called ‘physical dependence,’ which was said to be clinically unimportant. They cited studies with serious methodological flaws to highlight the entirely false claim that the risk of addiction was less than 1%.”⁹⁸

167. For example, in 1996, the APS and the AAPM – who were funded in part by the Producer Defendants – issued a “consensus statement” that “suggested that opioids were safe and effective for chronic, noncancer pain and that the risk of addiction was low.”⁹⁹

168. The co-authors of the Consensus Statement were David Joranson, MSSW, then

⁹⁵ *Id.* at 23-24.

⁹⁶ Paul Tough, *The Alchemy of OxyContin*, nytimes.com, July 29, 2001, <http://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html>.

⁹⁷ Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).

⁹⁸ *Id.*

⁹⁹ John Fauber, *Academics Profit by Making the Case for Opioid Painkillers*, abcnews.go.com, Apr. 4, 2011, abcnews.go.com/Health/academics-profit-making-case-opioid-painkillers/story?id=13284493.

founder and distinguished scientist of the Pain and Policy Studies Group at the University of Wisconsin School of Medicine and Public Health, and Haddox. Between 2000 and 2010, Joranson's Pain and Policy Studies Group received approximately \$1.6 million in grants from Purdue.¹⁰⁰ As detailed in an investigative series in the Milwaukee Journal Sentinel, the group became a consistent cheerleader for the widespread prescriptions of opioids. When he co-authored the Consensus Statement, Haddox was a paid speaker for Purdue. He was hired by Purdue in 1999 and has continued to be a Purdue executive ever since.¹⁰¹

169. Purdue further bolstered its fraudulent efforts with legislation in Tennessee and elsewhere as a part of national lobbying effort to promote opioids to treat chronic pain. In Tennessee, "legislators passed the Intractable Pain Treatment Act in 2001, a law requiring doctors to either prescribe opiates for pain or provide patients with a list of places they could get the drugs, including pain clinics."¹⁰² "When it was repealed in 2015, Sen. Janice Bowling, R-Tallahoma, said the original bill had been 'well-intentioned,' but was largely 'based on intentional misinformation' provided by Purdue at the time."¹⁰³ "With 11 minutes of deliberation, the Tennessee General Assembly passed what Purdue was telling states to do," said Bowling, who was not in the legislature in 2001, but later researched the bill. "The patient became the prescriber, if you will."¹⁰⁴

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² Clay Duda, *On the Front Lines of Knoxville's Battle Against Opiate Addiction*, [knoxvillemercury.com](http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/), June 1, 2016, <http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/>.

¹⁰³ *Id.*

¹⁰⁴ Rich Lord, *In 2001, Tennessee Gave Pain Physicians Green Light to Prescribe Opioids Without Repercussions*, [postgazette.com](http://www.post-gazette.com/news/nation/2016/05/26/In-2001-Tennessee-gave-pain-physicians-green-light-to-prescribe-opioids-without-repercussions/stories/201605250148), May 25, 2016, <http://www.post-gazette.com/news/nation/2016/05/26/In-2001-Tennessee-gave-pain-physicians-green-light-to-prescribe-opioids-without-repercussions/stories/201605250148> (quoting State Senator Janice Bowling).

iii. Purdue's 2007 guilty plea for lying about OxyContin, and its continued marketing of the drug

170. In 2007, Purdue and its three top executives were indicted and forced to plead guilty to wide ranging fraud in falsely promoting OxyContin as non-addictive and appropriate for chronic pain. Purdue's extensive fraud during the first two decades of its OxyContin campaign are thus an uncontroversial matter of public record admitted by the company.

171. As United States Attorney John L. Brownlee explained in a 2007 news release: "Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal."¹⁰⁵

172. As part of its 2007 felony guilty plea for misbranding OxyContin as less addictive and appropriate for chronic pain, Purdue admitted that:

Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:

[t]rained Purdue sales representatives and told some health care providers that it was more difficult to extract the OxyContin from an oxycodone tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton onto a syringe;

[t]old Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction

¹⁰⁵ WV Press Release, *surpa* note 48 (quoting U.S. Attorney John Brownlee).

than immediate-release opioids,[which the company knew was not true]; ...

[s]ponsored training that taught Purdue sales supervisors that OxyContin had fewer ‘peak and trough’ blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids, [which the company knew was not true];

[falsely] [t]old certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

[falsely] [t]old certain health care providers that OxyContin did not cause a ‘buzz’ or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to ‘weed out’ addicts and drug seekers.¹⁰⁶

173. As Purdue admitted in its 2007 guilty plea, these claims about OxyContin were entirely fraudulent. Nevertheless, for over 20 years they had been at the center of an unprecedented multi-million-dollar marketing campaign designed to convince physicians to disregard their longstanding unwillingness to prescribe opioids for any medical conditions other than late stage cancer and other acute, or short-term, conditions.

174. Under the plea agreement, Purdue also agreed to pay \$600 million in criminal and civil penalties – one of the largest settlements in history for a drug company’s marketing misconduct.¹⁰⁷

175. At the same time Purdue’s president, top lawyer, and medical director each pled guilty as individuals to criminal misbranding¹⁰⁸ and agreed to pay a total of \$34.5 million in

¹⁰⁶ *U.S. v. The Purdue Frederick Company, Inc.*, Case No. 1:07-cr-00029, Dkt. 5-2 (Agreed Statement of Facts) at ¶ 20 (W.D. Va. May 10, 2017).

¹⁰⁷ *U.S. v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571-72 (W.D. Va. 2007).

¹⁰⁸ “Misbranding” is a broad statute that makes it a crime to mislabel a drug, fraudulently promote it or market it for an unapproved use.

fines.¹⁰⁹

176. Under the plea agreement, Purdue also entered into a Corporate Integrity Agreement (“CIA”) with the United States Department of Health and Human Services – Office of Inspector General (“HHS-OIG”).¹¹⁰ As part of the CIA, Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the CIA, and to report its compliance (both independently and through an independent review organization) to the HHS-OIG.¹¹¹

iv. Even after its guilty plea, Purdue continued its false and misleading marketing practices aided by the other Producer Defendants

177. Despite its guilty plea, Purdue has continued to deceptively market opioids, feeding the opioid addiction crisis set in motion by its fraudulent advertising. As a result, sales of OxyContin were not only unhindered by the guilty plea – they continued to grow. OxyContin yielded \$3.1 billion in revenue for Purdue in 2010, which was nearly four times its 2006 sales of \$800 million.¹¹² The Producer Defendants joined in this effort.

178. Purdue continued to aggressively push the same false narrative for which it had been criminally prosecuted. To quote its statement of facts accompanying its guilty plea, the false narrative was that “OxyContin was less addictive, less subject to abuse” than traditional opioids, and therefore appropriate for treatment of long term chronic pain.

179. To evade scrutiny, Purdue continued to use third parties – with which it was closely tied financially – to convey its pro-OxyContin message.

¹⁰⁹ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, nytimes.com, May 10, 2007, <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

¹¹⁰ Information as to Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc., No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-5.

¹¹¹ *Id.*

¹¹² Katherin Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, Fortune.com, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

180. In addition to using front groups, Purdue masked its effort to continue the promotion of widespread opioid prescribing by presenting the decision to use opioids for chronic pain not as a highly risky practice with no scientific support – the truth – but rather as a complex determination that required extensive analysis of each individual patient. There was no scientific basis for this position, which effectively justified continued widespread opioid prescribing for virtually any patient, thereby allowing Purdue’s fraudulent marketing campaign to continue after 2007, as if the guilty plea had not occurred.

181. For example, in December 2009, medical education materials paid for by opioid manufacturers, including Endo and Purdue (1) reiterated Purdue’s core fraudulent claim that “addiction is rare in patients who become psychologically dependent on opioids while using them for pain control,” (2) emphasized the need to individually evaluate each patient “as clinical trials [rejecting opioid treatment] are not designed to identify the best treatment regimen in a given situation to manage chronic pain,” and (3) urged use of opioids even for patients engaging in “aberrant behaviors” while setting the following extreme standard to be used to identify individual patients with addiction problems: “a patient exhibiting egregious behaviors that persist, despite repeated warnings and that require significant time and resources to manage, is likely to have a problem with abuse and possibly addiction.” The materials further stated that “[a]n opioid trial is the only way a clinician can determine the efficacy and tolerability of a particular agent in a particular person” – in other words, the only way to rule out opioids for any given chronic pain patient was to give opioids a try. Not one of these assertions has ever been supported by science. Though “expired,” the materials are still available on the Internet today.¹¹³

182. In the same vein, Purdue-funded key opinion leader Dr. Russell Portenoy,

¹¹³ Anderson *et al*, “Opioid Prescribing: Clinical Tools and Risk Management Strategies, available at https://mn.gov/boards/assets/Opioid_Prsecibing_Clinical_Tools_and_Risk_Management_Strategies.pdf_tcm21-366993.pdf

speaking on Good Morning America in 2010, stated categorically that “[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.” As detailed in the scientific background section of this complaint, Dr. Portenoy’s bold assertion was directly contrary to the scientific evidence. Dr. Portenoy, who himself is facing lawsuits for his work as a Purdue-paid opioid pitchman, has now conceded that this promotion of opioids for chronic pain was “clearly the wrong thing to do.” He is on record stating: “I gave innumerable lectures in the late 1980s and 90’s about addiction that weren’t true.”¹¹⁴ But the damage has long since been done.

183. Another opioid pitchman, Dr. Lynn Webster, in 2010 disclosed serving on Purdue’s Medical Advisory Board. During the period of 2013 through 2015, Dr. Lynn Webster was the principle researcher on over \$9 million in contracts with pharmaceutical companies, including Mallinckrodt. Dr. Lynn Webster created a webinar out of a presentation he gave in Las Vegas, Nevada on September 22, 2011. In the Webinar, which remained available on the Internet on June 12, 2017, Webster promoted “Single-entity opioids (oxycodone, fentanyl)” for treatment of chronic pain.¹¹⁵ The seminar was, according to Dr. Webster, funded by a “generous education grant” from Purdue.

184. In 2016 and 2017, Webster also produced and distributed a 57-minute documentary, “The Painful Truth,” which continues to promote the use of opioids to treat chronic non-cancer pain. “The Painful Truth” tries to excuse Dr. Webster’s role in unleashing

¹¹⁴ Thomas Catan & Evan Perez, *A Pain Champion has Second Thoughts*, wsj.com, Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹¹⁵ See generally Emerging Solutions, <http://emergingsolutionsinpain.com/> (last visited June 12, 2017).

America's opioid addiction crises by featuring chronic pain patients expressing their fears about losing access to opioids.¹¹⁶

185. The 2010 annual report of the Producer Defendants-funded APF, which has been described by the President of Physicians for Responsible Opioid Prescribing as “a front for opioid manufacturers,”¹¹⁷ carefully documents the scope of the Producer Defendants' fraudulent enterprise. This 2010 report details thousands of pro-opioid advertisements, public statements, letters, Facebook Posts, and similar communications. For example, the report states: “Through online, print, radio, and television outlets, APF's local and national media outreach efforts secured 1,600 media stories on pain in 2010 – an increase of 1,255% from 2009. Reaching more than 600 million people with important pain-related messages, APF spokespeople and advocates provided education, information and assistance to people with pain and combated the negative stereotypes and stigmas associated with pain.”¹¹⁸

186. To this day, Purdue publishes an OxyContin website for physicians promoting OxyContin for patients with chronic pain – even those with a history of substance abuse. The site provides an example of a person suffering “sciatic nerve pain” with a history of substance abuse and states: “Risks are increased in patients with personal or family history of substance abuse ... [t]he potential for these risks should not, however, prevent the proper management of pain in any

¹¹⁶ David Armstrong, *TV Documentary on Pain Treatment Funded by Doctor with Industry Ties*, statnews.com, Mar. 24, 2017, <https://www.statnews.com/2017/03/24/pain-documentary-public-television/>.

¹¹⁷ Charles Ornstein and Tracy Weber, *Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Finds*, washingtonpost.com, Dec. 23, 2011. Available at: https://www.washingtonpost.com/national/health-science-/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html.

¹¹⁸ American Pain Fund 2010 Annual Report. Available at: https://archive.org/stream/277604-apf-2010-annual-report/277604-apf-2010-annual-report_djvu.txt.

given patient. Patients at increased risk may be prescribed opioids such as OxyContin.”¹¹⁹

187. These are not isolated statements, but just a select few representative examples of fraudulent pro-opioid communications that formed part of a vast, multi-year fraud designed to fuel the improper marketing of opioids following Purdue’s guilty plea by misrepresenting addiction risks and fraudulently promoting the entirely unscientific practice of using opioids for non-acute long term chronic pain.

188. The net effect of the Producer Defendants’ pro-opioid communications effort has been to continue the broad dissemination of the very lies for which Purdue pled guilty in 2007 up through this very day, thereby ensuring the continuous flow of opioids to Tennessee, and communities throughout the State, including Shelby County, without interruption.

189. Speaking before the House Opioid Task Force in 2017, Dr. Michael Baron of the Tennessee Board of Medical Examiners summed up the cumulative effect of the opioid manufacturers’ multi-year fraud:

We came out with what I call ‘Generation O.’ A whole generation of physicians that were taught it’s ok to prescribe opiates, that they’re safe, and that it’s what the patient wants. But we bypassed evidence-based medicine. The whole medical system was hijacked by industry and really greed.

The triggers of the opioid epidemic were really the pharmaceutical industry and pain experts that were on the payroll of the pharmaceutical industry. And they preached that opioids are safe and effective for chronic, non-cancer pain, the risk of addiction is rare, and opioid therapy can be easily discontinued, all of which is nonsense.¹²⁰

¹¹⁹ About OxyContin. Available at: <http://www.purduepharma.com/healthcare-professionals/products/oxycontin/> (last visited June 12, 2017).

¹²⁰ House Opioid Task Force, February 23, 2017.

v. Purdue profited from the abuse and diversion of OxyContin

190. The high availability of OxyContin correlated with increased addiction, abuse, and diversion (a term used to describe the redistribution of prescription drugs for illegal uses), and by 2004 OxyContin had become a leading drug of abuse in the United States.¹²¹

191. The increasing rates of addiction and abuse sustained OxyContin's remarkable commercial success.¹²² As the DEA has explained, OxyContin abusers learned how to simply crush the controlled-release tablet and swallow, inhale, or inject the high-potency opioid for an intense morphine-like high.¹²³ Purdue was well aware of this risk of diversion and abuse in this manner as early as 1995, because the company's own testing demonstrated that 68% of the oxycodone could be extracted from an OxyContin tablet when crushed.¹²⁴

192. In a November 2003 letter to the General Accounting Office ("GAO"), the DEA provided the following explanation of the causes and factors relating to the diversion of OxyContin:

The DEA has previously stated that the company's [i.e. Purdue's] aggressive methods, calculated fueling of demand and the grasp for major market share very much exacerbated OxyContin's widespread abuse and diversion. While Purdue highlights its funding of pain-related educational programs and websites and its partnership with various organizations, the fact remains that Purdue's efforts – which may be viewed as self-serving public relations damage control – would not have been necessary had Purdue not initially marketed its product aggressively and excessively. **Contributing to the abuse and**

¹²¹ Van Zee at 221.

¹²² *Id.* at 223.

¹²³ Drug Enforcement Administration, Office of Diversion Control, Action Plan to Prevent the Diversion and Abuse of OxyContin, https://web.archive.org/web/20080512200957/https://www.dea.gov/diversion/usdoj.gov/drugs_concern/OxyContin/abuse_oxy.htm (accessed May 4, 2017) [hereinafter *DEA OxyContin Action Plan*].

¹²⁴ Information as to Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc., No. 1:07-cr-00029, W.D. Va. May 10, 2007, ECF No. 5-5; *see also* Van Zee at 223.

diversion problem (and the product’s excessive availability) is the fact that in promoting this drug to practitioners, Purdue deliberately minimized the abuse risk associated with OxyContin The claim in Purdue’s “educational” video for physicians that opioid analgesics cause addiction in less than one percent of patients is not only unsubstantiated but also dangerous because it misleads prescribers.¹²⁵

193. In addition to DEA reports, the U.S. Department of Justice’s (“DOJ”) yearly drug market analysis of the Appalachia High Intensity Drug Trafficking Area (“Appalachia HIDTA”), provides an overview of opioid-related abuse and diversion in and around Tennessee.¹²⁶ As the DOJ explained in its 2009 drug market analysis:

The diversion, distribution, and abuse of controlled prescription drugs (CPDs) such as OxyContin (oxycodone), Vicodin (hydrocodone), and Valium (diazepam), are significant threats in the Appalachia HIDTA region. Traffickers and abusers illicitly obtain CPDs through traditional diversion methods (primarily doctor-shopping, theft, forged prescriptions, and unscrupulous physicians and pharmacists working alone or in association). Prescription drug traffickers and abusers increasingly circumvent law enforcement efforts to prevent CPD diversion in the region by obtaining drugs in Florida, Pennsylvania, and Tennessee.¹²⁷

194. The DOJ’s drug market analyses of the Appalachia HIDTA for the years 2008 through 2011 detail a steady rise in the availability and law enforcement seizures of oxycodone (primarily OxyContin) in the Tennessee illegal drug market: 1,069 dosage units of oxycodone seized in Tennessee in 2007;¹²⁸ 2,679 dosage units of oxycodone seized in Tennessee in 2008;¹²⁹

¹²⁵ *Id.* at 56.

¹²⁶ *See, e.g.*, U.S. Dep’t of Justice, *Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis*, 1-2 (June 2007) (explaining that the AHIDTA region “has a combined population of approximately 2.5 million” and “Knoxville, Tennessee, is the largest metropolitan area”).

¹²⁷ U.S. Dep’t of Justice, *Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis*, 2 (Mar. 2009).

¹²⁸ U.S. Dep’t of Justice, *Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis*, 4 (June 2008).

3,016 dosage units of oxycodone seized in Tennessee in 2009;¹³⁰ and 4,142 dosage units of oxycodone seized in Tennessee in 2010.¹³¹

195. More recently, a 2013 article in the L.A. Times revealed that, since at least 2002, Purdue has maintained a database of 1,800 doctors suspected of recklessly prescribing the company's pills to addicts and drug dealers.¹³² Purdue refers to the confidential list as "Region Zero" in internal documents.¹³³ In all but a few cases, Purdue did not alert law enforcement or medical authorities to the doctors on its list, many of whom were prolific prescribers of OxyContin.¹³⁴

196. The example of Dr. Elanor Santiago, one of the physicians on Purdue's "Region Zero" list, provides a stunning display of the causal relationship between the prescription market and diverted market for OxyContin, as well as Purdue's willful and knowing decision to profit from the diversion problem.

197. Beginning in the summer of 2008, Dr. Santiago, an elderly physician, ran the Lake Medical "clinic" (set up by an ex-con and his business partner) out of office space on a seedy block near MacArthur Park in Los Angeles.¹³⁵ Dr. Santiago immediately began prescribing OxyContin in extraordinary quantities. In a single week in September 2008, she issued orders for

¹²⁹ U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 4 (March 2009).

¹³⁰ U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 3 (May 2010).

¹³¹ U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 11 (Sept. 2011).

¹³² Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors*, latimes.com, Aug. 11, 2013, <http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811>.

¹³³ *Id.*

¹³⁴ *Id.* (noting that Purdue purportedly alerted law enforcement or medical regulators to 154 of the suspected prescribers – about 8% of those in its database).

¹³⁵ Harriet Ryan et al., *More than 1 million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, latimes.com, July 10, 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1,500 pills, more than entire pharmacies sold in a month. In October, it was 11,000 pills. By December, she had prescribed more than 73,000, with a street value of nearly \$6 million. Purdue tracked the surge in prescriptions, and eventually sent Michele Ringler, the district sales manager for Los Angeles, to check out the clinic as part of the company's investigation. When Ringler and one of her sales reps arrived, they found a building that looked abandoned, according to company emails recounting the visit. Inside, the hallways were strewn with trash and lined with a crowd of men who looked like they "just got out of L.A. County jail." Feeling uncomfortable, Ringler and the rep left without speaking to Dr. Santiago. When a Purdue security committee met in Stamford in December 2008, less than five months after Lake Medical opened, Dr. Santiago was under review, according to internal records and interviews. The panel, comprised of three company lawyers, could have reported Dr. Santiago to the DEA. Instead it opted to add her name to the "Region Zero" list of physicians suspected of recklessly prescribing OxyContin to addicts or dealers. As Purdue's investigation of the clinic continued, the company eventually concluded that Lake Medical was working with a corrupt pharmacy in Huntington Park to obtain large quantities of OxyContin. In a September 1, 2009 email Purdue district sales manager Ringler sent to company officials, she referred to the Lake Medical clinic and corrupt pharmacy as "an organized drug ring," and suggested that Purdue contact the DEA. Nevertheless, Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang, and other criminals.¹³⁶

198. Dr. Santiago's case is just one of many that demonstrate that Purdue did not use its database of suspected physicians to reduce OxyContin abuse, to rein in dangerous physicians,

¹³⁶ *Id.*

or to stop the unlawful distribution of opioids. Instead, Purdue knowingly aided criminal activity in order to maximize its own profits.

vi. Purdue failed to prevent diversion and to monitor, report, and stop suspicious orders of OxyContin as required

199. Purdue, as with all the Producer Defendants and Distributor Defendants, is under federal law duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids.

200. Like the Distributor Defendants, Purdue was required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids.¹³⁷ A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.¹³⁸

201. Additionally, as a registrant under Section 823, Purdue was also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual

¹³⁷ See 21 U.S.C. § 823(a).

¹³⁸ 21 U.S.C. § 823(a)(1).

frequency.¹³⁹

202. Purdue, as with all the Producer Defendants, had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Producer Defendants paid “chargebacks” to the Distributor Defendants. A chargeback is a payment made by a producer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a producer’s product to a pharmacy, for example, the distributor requests a chargeback from the producer and, in exchange for the payment, the distributor identifies to the producer the product, volume, and the pharmacy to which it sold the product. Thus, the Producer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Producer Defendants built receiving this information into the payment structure for the opioids provided to the Distributor Defendants.

203. For example, Purdue failed to take appropriate action in spite of knowing about unambiguous credible signs of abuse and diversion. Instead, Purdue continued to direct its sales team(s) to target the highest prescribers of OxyContin, including Shelby County, Tennessee providers, many of which were untrained in pain management.

204. On information and belief, Purdue called on two providers *48 times* after it had been told directly by law enforcement officials that the pair was responsible for significant interstate diversion of OxyContin and called on another provider *31 times* after the provider’s license was placed on restrictive probation because of issues related to his high prescribing of controlled substances. Purdue continued to make sales calls in spite of credible reports of patient

¹³⁹ 21 C.F.R. § 1301.74(b). *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”)

overdoses, indictments, adverse licensure actions, a provider admitting he was addicted to heroin, a knife fight outside of a provider's office, muggings over controlled substances outside of a pharmacy linked to a specific provider, a clinic that had no examination tables or equipment, an admission by a provider that he was running a pill mill, a provider changing the name of his practice shortly after he was notified of a state investigation into his practice, a patient being coached in the waiting room about how to fill out intake forms, armed guards in provider waiting rooms, high numbers of patients who purchased OxyContin in cash, high numbers of out-of-state or out-of-country tags in providers' parking lots, accusations of insurance fraud, choreographed urine screenings and pill counts, standing-room-only waiting rooms, and additional signs of problematic high volume practices.

205. By failing to prevent diversion and monitor, report, and stop suspicious orders of OxyContin, Purdue knowingly entered and participated in the marketing of illegal drugs in Tennessee. Purdue's actions and omissions have created and fueled a public nuisance in Tennessee by endangering the life and health of Shelby County residents. Purdue is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or 1.18 for every man, woman and child, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS Health data. By contrast, California with its population of 38.8 million people only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Tennessee Commissioner of Health Dreyzehner in his 2016 presentation, "Neonatal Abstinence Syndrome, a Tennessee Perspective," 51 hydrocodone pills and 21 oxycodone pills were prescribed for every Tennessean during the period covered by that report.

206. Purdue has knowledge of the fact that such inflated prescribing levels necessarily reflect illegal prescribing and diversion of opioids. On information and belief, Purdue had a replacement program for pharmacies whose inventories of Purdue opioid products were stolen or robbed that supplemented any amount of loss not covered by the pharmacy's insurance company. Purdue presented before the Governor's Working Group on or about September 11, 2015. At that presentation, Purdue conceded that "[t]he abuse of prescription opioid analgesics in the US is a significant public health problem," conceded that "OxyContin ... is subject to misuse, addiction, and criminal diversion," and conceded that even after the creation of purportedly abuse-resistant OxyContin, "abuse by these routes [injection and nasal], as well as the oral route, is still possible."

207. Purdue also gained knowledge of its participation in the illegal drug market in Tennessee through its knowledge of suspect and/or fraudulent OxyContin prescriptions and massive diversion of OxyContin based on, among other things, Purdue's own internal prescription tracking system and investigation, as well as notifications from pharmacies within Tennessee.

208. Purdue also presented a study of OxyContin abuse in rural Kentucky which showed that oral abuse of OxyContin and Oxycodone increased following the introduction of the abuse-resistant drugs. With full knowledge of the diversion risk, Purdue flooded the market without safeguards and ignored evidence of diversion where it was plain. As detailed elsewhere in this Complaint, Purdue further made misrepresentations regarding the properties of opioids, thereby knowingly causing illegal over-prescribing and giving rise to the addicts that require diversion to feed their habits.

209. Purdue further knowingly participated in the illegal drug market in Tennessee and

elsewhere promoting the abuse-deterrent properties of OxyContin, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other fraudulent conduct detailed in this Complaint. Those actions were designed to expand Purdue's market for opioids by inducing the medical community to overprescribe those drugs.

210. On information and belief, Purdue also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of OxyContin to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations (including 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b)), and otherwise circumventing Purdue's obligations under, for example, its own OxyContin Abuse and Diversion Detection Program.

B. Mallinckrodt

211. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in Shelby County and nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

212. Among the drugs Mallinckrodt manufactures and distributes are the following: Exalgo (hydromorphone hydrochloride extended release); Roxicodone (oxycodone hydrochloride); Xartemis XR (oxycodone hydrochloride and acetaminophen); Methadose (methadone hydrochloride); morphine sulfate extended release; fentanyl extended release; fentanyl citrate; oxycodone and acetaminophen; hydrocodone bitartrate and acetaminophen; hydromorphone hydrochloride; hydromorphone hydrochloride extended release; naltrexone hydrochloride; oxymorphone hydrochloride; methadone hydrochloride; oxycodone hydrochloride. Upon information and belief, Mallinckrodt distributed these drugs into the

Shelby County and Tennessee during the relevant time frame.

213. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.¹⁴⁰

i. Mallinckrodt funded false publications and presentations

214. Like several of the other Producer Defendants, Mallinckrodt provided substantial funding to KOLs and Front Groups, purportedly neutral doctors and organizations, which actually disseminated false messaging about opioids.

215. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as “a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.”

216. Among other content, the website included a handout titled “Oxycodone Safety Handout for Patients,” which advised practitioners that: “Patients’ fears of opioid addiction should be dispelled.”¹⁴¹ The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as addiction, a disease involving

¹⁴⁰ *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012). Available at: <http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE>.

¹⁴¹ Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007). Available at: <http://paincommunity.org/blog/wp-content/uploads/Oxycodone/Handout.pdf>.

craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.¹⁴²

217. Another document available on the website, “Commonsense Oxycodone Prescribing & Safety,” falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: “Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value ‘on the street,’ which also makes them less alluring for drug dealers.”¹⁴³

218. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb (“Gottlieb”), the new commissioner of the FDA, \$22,500 for a speech in London, shortly after the U.S. presidential election.¹⁴⁴ Gottlieb has also received money from the Healthcare Distribution Alliance, an organization funded by prescription drug manufacturers, including the Producer Defendants, that pushes the agenda of large pharmaceutical wholesalers and is an outspoken critic of efforts aimed at regulating the pharmaceutical opioid market.¹⁴⁵

ii. Tennessee drug task forces and the U.S. Drug Enforcement Agency (“DEA”) investigate suspicious orders of Mallinckrodt opioids

219. In 2011, to combat the opioid epidemic, the DEA began investigating Mallinckrodt, one of the nation’s largest manufacturers of oxycodone. As a Washington Post article explained, “[i]t was the first time the DEA had targeted a manufacturer of opioids for

¹⁴² *Id.*

¹⁴³ Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June 2007). Available at: <http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf>.

¹⁴⁴ Lee Fang, *Donald Trump’s Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, Intercept (Apr. 4, 2017, 2:15 PM). Available at: <https://theintercept.com/2017/04/04/scott-gottlieb-opioid/>.

¹⁴⁵ *Id.*

alleged violations of laws designed to prevent diversion of legal narcotics to the black market. It would become the largest prescription-drug case the agency has pursued.”¹⁴⁶ Relying on confidential government records and emails, the article further explained that the DEA and federal prosecutors had evidence Mallinckrodt “ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012 – 66 percent of all oxycodone sold in the state,” and that “the company’s lack of due diligence could have resulted in nearly 44,000 federal violations and exposed [Mallinckrodt] to \$2.3 billion in fines.”¹⁴⁷

220. In July 2017, Mallinckrodt agreed to a settlement of \$35 million with the DEA to resolve all allegations of criminal wrongdoing.¹⁴⁸ The settlement agreement stated that:

From January 1, 2008, through September 30, 2011, there was an epidemic increase in diversion of the controlled substance oxycodone, largely out of the state of Florida. [¶] The United States alleges that Mallinckrodt, a manufacturer and distributor of oxycodone, knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion. . . . [¶] The United States alleges that even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales. Furthermore, the United States alleges that Mallinckrodt never notified the DEA of the suspicious orders in violation of the [Controlled Substances Act].¹⁴⁹

221. As part of the settlement, Mallinckrodt admitted that, with respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt:

¹⁴⁶ Lenny Bernstein & Scott Higham, *The Government’s Struggle to Hold Opioid Manufacturers Accountable*, washingtonpost.com, April 2, 2017, https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.a0e6a4979116.

¹⁴⁷ *Id.*

¹⁴⁸ Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC (“Mallinckrodt MOA”) at 9.

¹⁴⁹ *Id.*

- failed to maintain effective controls against diversion;
- “[failed to] conduct adequate due diligence of its customers”;
- “[failed to] detect and report to the DEA orders of unusual size and frequency”;
- “[failed to] detect and report to the DEA orders deviating substantially from normal patterns”; and
- “[failed to] take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream.”¹⁵⁰

222. Mallinckrodt agreed to take the following prospective ameliorative steps, on top of its \$35 million settlement payment:

- “[d]esign and operate a system that meets the requirements of 21 CFR 1301.74(b);”
- design of a new suspicious order system;
- prospectively “notify the DEA of any diversion and/or suspicious circumstances;”
- maintain training, security, drug testing, and record keeping policies for its Hobart facility;
- issue record keeping policies consistent with DEA regulations; and
- set a quota for 2017 production that would not exceed its 2015 oxycodone production without DEA consent.¹⁵¹

223. A Washington Post article regarding Mallinckrodt’s settlement highlighted Tennessee’s connection to the DEA investigation. According to the article: “The first hint that Mallinckrodt might pose a problem for the DEA came not from Florida but from Tennessee. On July 7, 2009, members of a Tennessee drug task force in a sting operation seized several 100-tablet bottles of Mallinckrodt-made oxycodone. Task force agents alerted Mallinckrodt. The

¹⁵⁰ *Id.* at 2-3.

¹⁵¹ *Id.* at 4-8.

company's lot numbers were printed on the labels, allowing for easy tracking of the pills. Three days later, Mallinckrodt responded that the oxycodone had been prescribed by Barry Schultz, a doctor who ran a medical clinic in Delray Beach, Fla. The company said that one of its distributors, Sunrise Wholesale of Broward County, Fla., had sent 20,400 tablets of oxycodone to Schultz in the previous year.”¹⁵²

224. The article set out further significance of the Tennessee sting operation: **The DEA learned that in the six weeks following the Tennessee task force's alert to Mallinckrodt of the drugs found in the 2009 sting operation, the company still shipped another 2.1 million tablets of oxycodone to Sunrise.** The DEA also discovered that Sunrise had sent at least 92,400 tablets to Schultz over an 11-month period. In one day, he had prescribed 1,000 tablets to one patient.¹⁵³

225. At the time, the street value of oxycodone was \$30 a tablet. The Mallinckrodt drugs that Sunrise sent to Schultz after Mallinckrodt had already been notified of the Tennessee sting were worth nearly \$2.8 million on the street, according to prosecutors.¹⁵⁴

226. In an internal document sent to Mallinckrodt, the DEA stated: “When Mallinckrodt continued to distribute oxycodone to Sunrise for such purposes, and continued to pay incentives in the form of chargebacks for the product sales to Barry Schultz, Mallinckrodt was diverting oxycodone.”¹⁵⁵

¹⁵² Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, washingtonpost.com, April 2, 2017. Available at: https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.a0e6a4979116.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

iii. Mallinckrodt failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

227. In its July 2017 settlement agreement with Mallinckrodt, the DEA explained that:

Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as “chargebacks,” based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.¹⁵⁶

228. The 2017 settlement agreement confirms that, “[a]s a registrant under the [Controlled Substances Act of 1970 (“CSA”)], Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to the DEA.”¹⁵⁷ The settlement further confirms that, pursuant to its DEA authorization, Mallinckrodt had an “obligation” to only “distribute its drugs legally through legitimate channels.”¹⁵⁸

229. The United States alleged that Mallinckrodt neglected these duties: “Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious orders... Mallinckrodt never notified the DEA of the suspicious orders in violation of the CSA.”¹⁵⁹

230. The 2017 settlement agreement details the allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid producer to prevent diversion.¹⁶⁰

¹⁵⁶ Mallinckrodt MOA at 9.

¹⁵⁷ *Id.* at 1.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 2-3.

231. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Mallinckrodt knowingly entered and participated into the marketing of illegal drugs in Tennessee. Mallinckrodt is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. As noted previously, in 2015 Tennessee doctors wrote more than 7.8 million opioid prescriptions — or 1.18 prescriptions for every single Tennessean, more than double California's contemporaneous rate of 0.48 prescriptions per capita, and ranking Tennessee second in the nation for per capita prescriptions. Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. On average, 51 hydrocodone pills and 21 oxycodone pills were prescribed for every Tennessean in 2016. Mallinckrodt knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt's products.

232. Mallinckrodt further knowingly participated in the illegal drug market in Tennessee and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders, for which it was cited by the DEA, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Mallinckrodt's market for opioids by inducing the medical community to overprescribe those drugs.

233. On information and belief, Mallinckrodt also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

C. Endo

234. Endo manufactures, markets, sells, and distributes pharmaceutical drugs in Shelby

County and nationwide.

235. Among the drugs Endo manufactures and distributes are the following: Opana (oxymorphone hydrochloride); Opana ER (oxymorphone hydrochloride extended release); Percodan (oxymorphone hydrochloride and aspirin); Percocet (oxymorphone hydrochloride and acetaminophen); oxycodone; oxymorphone; hydromorphone; hydrocodone. Upon information and belief, Endo distributed all of these drugs in Tennessee and in Shelby County during the relevant time frame.

236. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated “for the relief of moderate to severe pain” and “for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction.” However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.

237. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was “indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate.” Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated “for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.” Endo’s goal was to use Opana ER to take market share away from OxyContin; thus it was marketed as being safer, with less abuse potential than OxyContin because of its crush-resistance.

238. According to Endo’s annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from \$107

million in 2007 to as high as \$384 million in 2011. Over the last ten years, Percocet has generated an average of well over \$100 million in annual revenue for the company.

i. Endo falsely marketed Opana ER as crush resistant

239. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered “safety advantages” over the original formulation because the latter “is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets.’”

240. Endo publicized the reformulated version of Opana ER as “crush-resistant.” To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release. In a December 12, 2011, press release announcing FDA approval of the reformulated Opana ER, Endo’s executive vice president for research and development and chief scientific officer highlighted the reformulated version’s safety characteristics:

FDA’s approval of this new formulation of Opana ER is an important milestone for both the Long Acting Opioid category as well as Endo’s branded pharmaceutical portfolio. . . . Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers.

241. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER.

242. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for insufflation (snorting) using commonly available tools and methods," and "can [be readily] prepared for injection." It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

243. Endo continued to promote the purported abuse-deterrent properties of Opana ER despite the fact that Endo executives knew that both the original and reformulated Opana ER were being widely abused. In an internal Endo document from February 2013, an Endo consultant reported, after reviewing national data from substance abuse treatment facilities, that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant," and that there were reports of higher levels of abuse of reformulated Opana ER via injection.¹⁶¹

244. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that, although overall abuse of Opana had fallen following Opana ER's reformulation, injection had become the preferred way of abusing the drug. However, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

245. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of

¹⁶¹ See, e.g., *In re: Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 at 5, March 2016. Available at: <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>. [Hereinafter "NY AG Settlement"].

“a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs.”¹⁶² The CDC specifically attributed the outbreak to the injection of Opana ER:

From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.¹⁶³

ii. New York’s investigation found Endo falsely marketed Opana ER

246. Endo’s misrepresentations regarding the properties of Opana ER, and failure to accurately describe the drug’s risk of addiction, drew the attention of the Attorney General of the State of New York (“NY AG”), who opened an investigation into the company’s marketing practices.

247. In March 2016, the NY AG and Endo reached an agreement ending the investigation. In connection with the 2016 settlement agreement, the NY AG found there was no evidence to support Endo’s claim – made on Endo’s website, www.opana.com, and elsewhere – that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”¹⁶⁴ Consistent with that finding, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most

¹⁶² *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention. Available at: <https://emergency.cdc.gov/han/han00377.asp> (last visited Jan. 2, 2018).

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 15.

patients who take opioids do not become addicted” in New York.¹⁶⁵

248. In the 2016 settlement, Endo further agreed not to make statements in New York that Opana ER was “designed to be, or is crush resistant.”¹⁶⁶ The NY AG found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the CDC’s “Guideline for Prescribing Opioids for Chronic Pain – United States, 2016” states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies, even when they work, “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”¹⁶⁷

249. The 2016 settlement also addressed Endo’s misleading use of the term “pseudoaddiction.” As the NY AG found:

Endo also trained its sales representatives to distinguish addiction from “pseudoaddiction,” a purported condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. The “pseudoaddiction” concept has never been empirically validated and in fact has been abandoned by some of its proponents. Endo’s Vice President for Pharmacovigilance and Risk Management testified to OAG that he was not aware of any research validating the “pseudoaddiction” concept.¹⁶⁸

250. Based on that finding, the 2016 settlement prohibits Endo from “us[ing] the term ‘pseudoaddiction’ in any training or marketing” in New York.¹⁶⁹

251. Critically, the 2016 settlement highlighted Endo’s failure to set up an effective system for identifying and reporting suspicious prescribing. To this end, the NY AG found that

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 5-6.

¹⁶⁷ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, at 22, March 18, 2016. Available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>.

¹⁶⁸ NY AOG Settlement at 7.

¹⁶⁹ *Id.* at 15.

Endo:

- failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing;
- paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and
- failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.¹⁷⁰

252. Endo's misconduct is not limited to New York. Upon information and belief, in Shelby County and throughout Tennessee, Endo and its sales representatives knowingly utilized the same false and misleading marketing practices for Opana ER, and falsely claimed that the risk of addiction to the drug was low, or even non-existent.

iii. Endo funded false publications and presentations

253. Like several of the other Producer Defendants, Endo provided substantial funding to KOLs and Front Groups, purportedly neutral individuals and medical organizations that instead promoted the Producer Defendants' agenda, including APF.

254. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."

255. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide

¹⁷⁰ *Id.* at 9-12.

meaningful relief.

256. The article included a case study that focused on the danger of extended use of nonsteroidal anti-inflammatory drugs, commonly referred to as “NSAIDs” and a common way to treat pain without using opioids. The case study’s subject had been hospitalized with a massive upper gastrointestinal bleed believed to have been caused by his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that “use of opioids may be effective in the management of chronic pain.”

257. Later, in 2014, Endo issued a patient brochure titled “Understanding Your Pain: Taking Oral Opioid Analgesics.” It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

258. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

Addiction **IS NOT** when a person develops “withdrawal” (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal “tolerance” to opioid medications doesn’t affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will “run out” of pain relief. Your dose can be adjusted or another medicine can be prescribed.

How can I be sure I’m not addicted?

- Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.

Your doctor or nurse may instruct you to do some of the following:

- Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.
- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.
- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.¹⁷¹

259. In 2008, Endo also provided an “educational grant” to PainEDU.org, which produced a document titled “Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q.”¹⁷² SOAPP describes itself “as a tool for clinicians to help determine how

¹⁷¹ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004). Available at: http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (last visited Jan. 2, 2018).

¹⁷² B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium 2* (Am. Society of Pain Educators 2009). Available at: <https://www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf> (last visited Jan. 2, 2018).

much monitoring a patient on long-term opioid therapy might require.” SOAPP falsely refers to purportedly “recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems.”

260. Endo also sponsored the now-defunct website painknowledge.com, which was created by APF to be “a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches.” Among other featured content, painknowledge.com included a flyer titled “Pain: Opioid Therapy,” which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence, and addiction.

261. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, the literature promoting opioids for combat veterans’ pain discussed above.

iv. FDA requests Endo withdraw Opana ER due to the public health consequences of abuse

262. The ongoing and excessive abuse of Opana ER reached such a critical level that on June 8, 2017, the FDA took the unprecedented step of demanding that Endo permanently remove the drug from the marketplace.¹⁷³ According to a FDA press release, the agency’s “decision [was] based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product’s reformulation.”¹⁷⁴ The FDA decided to remove the opioid from the marketplace followed a March 2017 FDA advisory committee meeting where a group of truly independent

¹⁷³ FDA Press Release. *FDA requests removal of Opana ER for risks related to abuse*. June 8, 2017. Available at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

¹⁷⁴ *Id.*

experts voted that “the benefits of reformulated Opana ER no longer outweigh its risks.”¹⁷⁵

263. On July 6, 2017, Endo announced that it would voluntarily remove Opana ER from the market, citing the FDA’s concerns of diversion.¹⁷⁶

264. Endo’s current conduct merits special condemnation. In connection with its unsuccessful petition to have reformulated Opana ER designated as tamper-resistant, Endo publicly advocated that its *original* formulation of Opana ER is so dangerous and susceptible to abuse and diversion that it should be taken off the market.¹⁷⁷ Endo represented, *inter alia*, that its own testing shows that “96% of research subjects were willing to snort the Original Formulation (which could be crushed into powder).”¹⁷⁸ It argued that allowing the Original Formulation onto the market “*will result in increases in drug abuse, misuse and diversion,*” and that “[s]erious and predictable public harm would flow from entry and continued sale” of that product. Endo voluntarily removed that original formulation of Opana ER on the basis of those stated safety concerns. Thereafter, *Endo sued the FDA*, seeking a preliminary injunction to prevent generic versions of the original Opana ER from coming onto the market. It represented to a federal court as follows:

Unless the Court intervenes and issues an injunction to preserve the status quo, on January 1, 2013, a generic version of the Original Formulation drug will be released. If this occurs . . . the public interest will be substantially and irreparably injured by release of generic versions of a drug which relies upon a drug that was withdrawn for safety reasons and that is subject to abuse and misuse that FDA

¹⁷⁵ *Id.*

¹⁷⁶ CBS News online. *Opana ER opioid painkiller pulled from the market by FDA request*. July 7, 2017. Available at: <https://www.cbsnews.com/news/drug-opana-er-opioid-painkiller-pulled-from-the-market-by-fda/> (last visited Dec. 28, 2017).

¹⁷⁷ <https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html>; see also *Endo Pharm. v. U.S. Food & Drug Admin., et al.*, Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 13 (stating that Endo represented to the FDA that permitting a generic manufacturer to introduce a generic equivalent to the original Opana ER “would allow abuse or diversion to continue . . .”).

¹⁷⁸ *Id.* at p. 14.

acknowledges and against which it has long fought.

...

Unless the Court intervenes and issues a preliminary injunction, there is a significant risk that a readily crushable, and thus admittedly less safe, opioid drug will serve as the RLD for generic drugs that will then be subject to abuse and misuse. FDA inaction will have facilitated precisely the type of harm to the public interest against which it has fought for many years.¹⁷⁹

Endo also argued that introducing the generic equivalent “*will result in drug abuse, misuse and diversion with a predictable upsurge in serious injuries and overdose deaths.*”¹⁸⁰

265. Thus, in 2012, Endo publicly acknowledged that it knew that original Opana ER was highly susceptible to abuse and diversion, that it was such a threat to public health and safety that neither it nor any equivalent should be allowed on the market, that diversion and adverse public health effects (including “serious injuries and overdose deaths”) are “predictable” consequences of producing and distributing opioids that are subject to abuse.

266. Nevertheless, after the new Opana ER formulation was removed from the market at the FDA’s request in July 2017, Endo pivoted and entered into a contract with Impax to *share profits* from sales of a generic equivalent to the *original Opana ER* sold under the “Impax” name. The agreement allows for profit-sharing for the next 11 years, starting January 1, 2018. As numerous observers have pointed out, “Endo is profiting off of the very drug it said was unsafe to stay on the market.”¹⁸¹ By Endo’s own admission, continuing to distribute this product “will result in increases in drug abuse, misuse and diversion,” along with “serious and predictable public harm.” Accordingly, Endo has known all along that streaming its opioid products into communities “predictably” results in high levels of addiction, overdose death, and

¹⁷⁹ *Id.* at p. 3.

¹⁸⁰ *Id.*

¹⁸¹ <https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html>.

illegal diversion – but it does not care, so long as it continues to turn a profit.

v. Endo failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

267. Endo is a “registrant” under the Controlled Substances Act as a manufacturer of Schedule II controlled substances.¹⁸²

268. The CSA imposes on all “registrants” the obligation to design and operate a system to disclose orders of controlled substances, and also requires registrants to notify their local DEA field division office of any suspicious orders. Suspicious orders are defined to “include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”¹⁸³

269. Endo failed to design and operate a system to disclose suspicious orders of controlled substances.

270. Endo further failed to notify the appropriate DEA field division of suspicious orders.

271. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Endo knowingly entered into and participated in the market for illegal drugs in Tennessee. Endo is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. As noted previously, in 2015 Tennessee doctors wrote more than 7.8 million opioid prescriptions — or 1.18 prescriptions for every single Tennessean, more than double California’s contemporaneous rate of 0.48 prescriptions per capita, and ranking Tennessee second in the nation for per capita prescriptions. Tennessee’s oxycodone prescription rate is twenty-two times that of Minnesota’s. On average, 51 hydrocodone pills and 21 oxycodone pills were prescribed for every Tennessean in 2016. Endo knew that such inflated

¹⁸² 21 C.F.R. §1300.02(b); 21 U.S.C. § 823.

¹⁸³ 21 C.F.R. §1301.74(b).

prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt's products.

272. Endo further knowingly participated in the illegal drug market in Tennessee and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders. In fact, Endo was cited by the DEA for deliberately and knowingly downplaying addiction risks associated with opioids and through the knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Endo's market for opioids by inducing the medical community to overprescribe those drugs.

273. On information and belief, Endo also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing these suspicious orders as required by applicable regulations.

D. Cephalon

274. Cephalon manufactures, markets, sells and distributes pharmaceutical drugs in Shelby County and nationwide.

275. Among the drugs Cephalon manufactures and distributes are the following: Actiq (fentanyl citrate); Fentora (fentanyl buccal); oxycodone hydrochloride. Upon information and belief Cephalon distributed these drugs into Shelby County and Tennessee during the relevant time frame.

276. Actiq is designed to resemble a lollipop that cancer patients are instructed to suck at the onset of intense breakthrough pain ("BTP"). It rapidly delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine, into the patient's bloodstream through the

oral membranes.¹⁸⁴ Because it is absorbed through these membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.

277. In November 1998, the FDA approved Actiq for a very narrow group of people – cancer patients “with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹⁸⁵

278. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA’s approval of Actiq was specifically worded as “**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹⁸⁶ Further, the FDA explicitly required that Actiq “**must not** be used in opioid non-tolerant patients.” The FDA also contraindicated Actiq for the management of acute or postoperative pain and noted that it could be deadly to children and was “intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.”

279. The FDA further required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug’s direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.

280. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

281. Cephalon also purchased the rights to Fentora, an even faster-acting tablet

¹⁸⁴ John Carreyrou, *Narcotic “Lollipop” Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006). Available at: <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/> (last visited Jan. 2, 2018).

¹⁸⁵ 1998 FDA Label.

¹⁸⁶ NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation.

formulation of fentanyl, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA highly qualified approval to sell this faster-acting version of Actiq. Once again, concerned with the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

i. Cephalon aggressively marketed its cancer drugs to non-cancer treating physicians

282. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries, and other chronic non-cancer pain. Cephalon targeted non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists, and sports clinics, an act clearly in violation of applicable regulations prohibiting marketing medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients through oncologists and pain management doctors experienced in treating cancer pain.

283. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased sixfold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons, each good for six free Actiq lozenges, and encouraging prescribers to prescribe Actiq to their non-cancer patients.¹⁸⁷

¹⁸⁷ Carreyrou, *Narcotic Lollipop*.

284. Cephalon's efforts paid off. In 2000, Actiq generated \$15 million in sales.¹⁸⁸ By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."¹⁸⁹ By 2005, Actiq's sales total had jumped to \$412 million, making it (a drug approved for only a narrow customer base) Cephalon's second-best-selling drug. By the end of 2006, Actiq's sales had exceeded \$500 million.¹⁹⁰

285. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."¹⁹¹

ii. Government investigations found Cephalon falsely marketed Actiq for off-label uses

286. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

287. According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs, and funded CME courses to promote off-label uses. Specifically, the DOJ stated:

¹⁸⁸ *Id.*

¹⁸⁹ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003).

¹⁹⁰ Carreyrou, *Narcotic Lollipop*.

¹⁹¹ *Id.*

From 2001 through at least 2006, *Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.*¹⁹²

288. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.¹⁹³

289. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician

¹⁹² Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008). Available at:

<https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

¹⁹³ *Id.*

that Actiq does not cause patients to experience a “high” and carries a low risk of diversion toward recreational use;

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;
- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.¹⁹⁴

290. Nevertheless, Cephalon continued its deceptive marketing strategy for both Actiq and Fentora.

iii. Cephalon focused on non-cancer treating physicians in falsely marketing Fentora

291. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe and effective off-label treatment for non-cancer pain, and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

292. During an investor earnings call shortly after Fentora’s launch, Cephalon’s chief executive officer (“CEO”) described the “opportunity” presented by the use of Fentora for non-cancer pain:

¹⁹⁴ John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, at B1 (hereinafter “Carreyrou, *Cephalon Used Improper Tactics*”).

The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain.

Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.

We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well being and the exciting growth potential that it has for Cephalon.

In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.¹⁹⁵

iv. The FDA warned Cephalon regarding its false and off-label marketing of Fentora

293. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.”¹⁹⁶

294. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for

¹⁹⁵ Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call, at 6-7 (May 1, 2007). Available at: <http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?all=true&find=Q1%2B2007%2BCephalon%2BMay%2B1%2C%2B2007>.

¹⁹⁶ Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007).

Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.¹⁹⁷ An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

295. Despite Cephalon's revisions, in 2009 the FDA once again informed Cephalon that its risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

296. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

297. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the that purpose, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

298. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy*

¹⁹⁷ *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008).

Times titled “An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: “It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain.”¹⁹⁸

v. Cephalon funded false publications and presentations

299. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic long-term pain, that opioids were non-addictive, and that opioids were woefully under-prescribed to the detriment of patients who were needlessly suffering. Cephalon did so by sponsoring pro-opioid Front Groups that developed misleading prescription guidelines, articles, and CMEs, and it paid KOLs thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

300. Cephalon and its Front Groups sponsored numerous CMEs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and disseminated false and misleading information to physicians in Shelby County and across the country.

301. For example, a 2003 Cephalon-sponsored CME presentation on Medscape titled “Pharmacologic Management of Breakthrough or Incident Pain” teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly

¹⁹⁸ *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012).

*regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.*¹⁹⁹

302. Another Cephalon-sponsored CME presentation titled “Breakthrough Pain: Treatment Rationale with Opioids” was posted to Medscape on September 16, 2003 and was delivered by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”²⁰⁰ The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.

303. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled “Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines.”²⁰¹ This literature purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing

¹⁹⁹ Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803> (last visited Jan. 2, 2018).

²⁰⁰ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last visited Jan. 2, 2018).

²⁰¹ Gerald M. Aronoff, *et al.*, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).

guidelines in both cancer and non-cancer patients. In pertinent part, it states:

Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients.***²⁰²

304. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

Alternatively, ***OTFC might also be used cautiously and safely for acute pain experienced by patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant.*** Examples include episodic pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.²⁰³

305. Through its sponsorship of the previously referenced Front Group FSMB's "Responsible Opioid Prescribing: A Physician's Guide," Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

306. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an annual meeting for the previously-referenced Front Group

²⁰² *Id.*

²⁰³ *Id.*

AAPM that was held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled “Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT [use of fentanyl effervescent buccal tablets] is safe and well-tolerated in patients with chronic pain and BTP.”

307. Cephalon sponsored yet another Medscape CME written by Webster and M. Beth Dove titled “Optimizing Opioid Treatment for Breakthrough Pain” which was available from September 28, 2007 through December 15, 2008. The CME teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.²⁰⁴

308. KOL Fine authored a Cephalon-sponsored CME titled “Opioid-Based Management of Persistent and Breakthrough Pain,” with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME published in a “Special Report” supplement of the journal *Pain Medicine News* in 2009.²⁰⁵ The CME targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating “health care professionals about a semi-structured approach to the opioid-based

²⁰⁴ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Jan. 2, 2018).

²⁰⁵ Perry G. Fine, *et al.*, *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9>.

management of persistent and breakthrough pain,” including the use of fentanyl. The CME purports to analyze the “combination of evidence- and case-based discussions” and ultimately concludes:

Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. *All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial of opioid therapy, although not all of them will be selected.*²⁰⁶

309. Along with Purdue, Cephalon sponsored APF’s guide, which warned against the purported *under*-prescribing of opioids, taught that addiction is *rare* and suggested that opioids have “*no ceiling dose*” and are therefore the most appropriate treatment for severe pain.

310. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that “the undertreatment of pain is unjustified.” It continues:

Pain management is a fundamental human right in all patients not only with acute postoperative pain but also *in patients suffering from chronic pain*. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.²⁰⁷

311. In a March 2007 article titled “Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral

²⁰⁶ *Id.*

²⁰⁷ Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) *Advances in Pain Management* 50-52 (2008).

Transmucosal Fentanyl Citrate,”²⁰⁸ published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including notorious KOL Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the “OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.”²⁰⁹ The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with *chronic noncancer pain* and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP *and the potential benefits of BTP-specific therapy* suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²¹⁰

312. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik (“Passik”), Dr. Kenneth L. Kirsh (“Kirsh”), and Webster, all advancing the safety and efficacy of opioids. In an article titled “Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients,” Webster expresses disdain for the prior 20 years of opioid phobia.

313. In another article from the same issue, “Appropriate Prescribing of Opioids and Associated Risk Minimization,” Passik and Kirsh state: “[c]hronic pain, currently experienced by

²⁰⁸ Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

²⁰⁹ *Id.*

²¹⁰ *Id.*

approximately 75 million Americans, is becoming one of the biggest public health problems in the US.” They assert that addiction is rare, that “[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function” and that then-recent work had shown “that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction.”²¹¹

314. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”²¹² In that article, Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledges that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” of this use of opioids had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”²¹³

315. They conclude: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related

²¹¹ Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) *Advances in Pain Management* 9-16 (2008).

²¹² Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) *J. Pain & Symptom Management* 747-60 (Nov. 2010).

²¹³ *Id.*

events was “small.”²¹⁴

316. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included KOLs like Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

317. Cephalon’s payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.²¹⁵ A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that “the approaches taken . . . [did] not uniformly reflect clinical practice” and that “the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias.”²¹⁶

vi. Cephalon failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

318. Cephalon is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires.

319. The federal CSA imposes on all “registrants” the obligation to design and operate a system to disclose suspicious orders of controlled substances and requires registrants to notify their local DEA field division office of any suspicious orders. “Suspicious orders include orders

²¹⁴ *Id.*

²¹⁵ Carreyrou, *Cephalon Used Improper Tactics*.

²¹⁶ Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²¹⁷

320. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

321. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Cephalon knowingly entered and participated in the marketing of illegal drugs in Tennessee. Cephalon is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. As noted previously, in 2015 Tennessee doctors wrote more than 7.8 million opioid prescriptions — or 1.18 prescriptions for every single Tennessean, more than double California’s contemporaneous rate of 0.48 prescriptions per capita, and ranking Tennessee second in the nation for per capita prescriptions. On average, 51 hydrocodone pills and 21 oxycodone pills were prescribed every Tennessean in 2016, and Tennessee’s oxycodone prescription rate is twenty-two times that of Minnesota’s. Cephalon knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt’s products.

322. Cephalon, through the affiliated Defendant Teva, is also one of the top producers of generic oxycodone and hydrocodone in Shelby County and throughout the State of Tennessee.

323. Cephalon further knowingly participated in the illegal drug market in Tennessee and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Cephalon’s market for opioids by inducing the medical community to overprescribe

²¹⁷ 21 C.F.R. §1301.74(b).

those drugs and prescribe those drugs to inappropriate patients.

324. On information and belief, Cephalon also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

E. Janssen

325. Janssen manufactures, markets, sells and distributes pharmaceutical drugs in Shelby County and nationwide.

326. Among the drugs Janssen manufactures and distributes are the following: Duragesic (fentanyl); Nucynta (tapentadol hydrochloride); Nucynta ER (tapentadol hydrochloride extended release). Upon information and belief, Janssen distributed these drugs in Shelby County and Tennessee during the relevant time frame.

327. Janssen introduced Duragesic in 1990. It is indicated for the “management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

328. Janssen also produces and markets Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”

329. Additionally, Janssen produces and markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the “management of... pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” This pain indication was later altered to “management of moderate to severe chronic pain in adults” and “neuropathic pain associated

with diabetic peripheral neuropathy (DPN) in adults.” Janssen sold Nucynta and Nucynta ER to another opioid manufacturer, Depomed, in 2015 for \$1.05 billion.

i. The FDA warned Janssen regarding its false messaging

330. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of “homemade” promotional pieces that promoted Duragesic in violation of the FD&C Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.”

331. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

You present the claim, “Low abuse potential!” This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, “Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine.” Therefore, this claim is false or misleading.²¹⁸

332. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.” Specifically, the FDA stated that Janssen was marketing Duragesic for indications beyond the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

You present the claim, “It’s not just for end stage cancer anymore!” This claim suggests that Duragesic can be used for any

²¹⁸ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica, at 2 (Mar. 30, 2000).

type of pain management. However, the PI for Duragesic states, “Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means” Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states: “BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED: ... In the management of acute or post-operative pain, including use in out-patient surgeries”²¹⁹

333. The March 30, 2000 letter further stated Janssen failed to adequately present “contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product”:

Although this piece contains numerous claims for the efficacy and safety of Duragesic, *you have not presented any risk information* concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic’s use Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.²²⁰

334. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.”

²¹⁹ *Id.* at 2-3.

²²⁰ *Id.* at 3 (emphasis in original).

335. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network (“DAWN”) as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic’s lower frequency of use compared to other opioids listed in DAWN:

The file card presents the prominent claim, “Low reported rate of mentions in DAWN data,” along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.

This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.

Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.²²¹

336. The September 2, 2004 letter also details a series of unsubstantiated, false or misleading claims regarding Duragesic’s effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported.²²²

²²¹ Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004).

²²² *Id.* at 2-3.

337. In addition, the September 2, 2004 letter identifies “outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic.” The claims include “‘1,360 loaves . . . and counting,’ ‘[w]ork, uninterrupted,’ ‘[l]ife, uninterrupted,’ ‘[g]ame, uninterrupted,’ ‘[c]hronic pain relief that supports functionality,’ ‘[h]elps patients think less about their pain,’ and ‘[i]mprove[s] . . . physical and social functioning.’” The September 2, 2004 letter states: “Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims.”²²³

338. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been “‘examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch’” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

339. Regardless, even after receiving these letters, Janssen instructed its sales representatives to market Duragesic as having better efficacy, better tolerability and better patient compliance because it was a patch instead of a pill. Janssen’s sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing, then chewing on it.

²²³ *Id.* at 3.

ii. Janssen funded false publications and presentations

340. Despite repeated warnings, Janssen continued to falsely market the risks of opioids. In 2009, PriCara, a “Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.,” sponsored a 2009 brochure, “Finding Relief: Pain Management for Older Adults,” aimed at potential patients. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.

You will learn about your options for pain management and how to find the treatment that’s right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.²²⁴

341. Despite representing itself as a source of accurate information, the brochure included false and misleading information about opioids, including a section seeking to dispel purported “myths” about opioid usage:

Opioid Myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

²²⁴ *Finding Relief, Pain Management for Older Adults* (2009).

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.²²⁵

342. Among the “Partners” listed in “Finding Relief: Pain Management for Older Adults” are Front Groups the AAPM, the American Geriatrics Society (“AGS”) and the AGS Foundation for Health in Aging. Janssen (along with Purdue and Endo) funded AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled “Finding Relief: Pain Management for Older Adults,” which was funded by Janssen.

343. In addition, Janssen disseminated false information about opioids on the website “Prescribe Responsibly,” which remains publicly accessible at www.prescriberesponsibly.com. According to the website’s legal notice, all content on the site “is owned or controlled by Janssen.”²²⁶ The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to “questions of addiction,” such concerns “are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic[] . . . therapy.”²²⁷

344. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

Opioid analgesics are often the first line of treatment for many

²²⁵ *Id.*(emphasis in original).

²²⁶ *Legal Notice*, Prescribe Responsibly. Available at: <https://www.prescriberesponsibly.com/legal-notice> (last visited Jan. 2, 2018).

²²⁷ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly. Available at: <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Jan. 2, 2018)

painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true ‘ceiling dose’ for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.²²⁸

345. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of “pseudoaddiction” as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.”²²⁹ Thus, pseudoaddiction is defined as a condition requiring the prescription of more or stronger opioids.

iii. Janssen failed to prevent diversion and to monitor, report, and stop suspicious orders of its prescription opioid products as required

346. Janssen is a “registrant” under the federal CSA.

347. The federal CSA imposes on all “registrants” the obligation to design and operate a system to disclose suspicious orders of controlled substances and requires registrants to notify their local DEA field division office of any suspicious orders. “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²³⁰

348. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

²²⁸ *Id.*

²²⁹ *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly. Available at: <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids> (last visited Jan. 2, 2018).

²³⁰ 21 C.F.R. §1301.74(b).

349. By failing to prevent diversion and monitor, report, and stop suspicious orders of its prescription opioid products, Janssen knowingly entered and participated in the marketing of illegal drugs in Tennessee. Janssen is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. As noted previously, in 2015 Tennessee doctors wrote more than 7.8 million opioid prescriptions — or 1.18 prescriptions for every single Tennessean, more than double California's contemporaneous rate of 0.48 prescriptions per capita, and ranking Tennessee second in the nation for per capita prescriptions. On average, 51 hydrocodone pills and 21 oxycodone pills were prescribed every Tennessean in 2016, and Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. Janssen knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Janssen's products.

350. Janssen further knowingly participated in the illegal drug market in Tennessee and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Janssen's market for opioids by inducing the medical community to overprescribe those drugs and prescribe those drugs to inappropriate patients.

351. On information and belief, Janssen also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

V. The Distributor Defendants' Unlawful Conduct

A. The Distributor Defendants have a duty to report and stop suspicious orders of prescription opioids

352. Distributor Defendants have an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs that they distribute.

353. Congress created a closed system of distribution of prescription opioids with the Controlled Substance Act of 1970 (“CSA”) that required all manufacturers and distributors to obtain registrations and investigate, report, and stop suspicious orders of prescription opioids.

354. The closed loop system established by the CSA combats diversion by requiring that “all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion.”²³¹

355. The CSA and its implementing regulations restrict the distribution of controlled substances by requiring drug distributors and manufacturers to monitor, identify, stop, and report suspicious orders of controlled substances, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.²³²

356. The Distributor Defendants are required to register with the DEA, pursuant to the CSA.²³³ Accordingly, each of the Defendant Distributors is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances (opioids) with a duty to comply with all security requirements imposed under that statutory scheme.

357. In evaluating a distributor’s operations, the DEA considers “(1) whether the

²³¹ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Sept. 27, 2006, at 1 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (D.D.C.)). (hereinafter “2006 Rannazzisi Letter”)

²³² See 21 U.S.C. §§ 801-971; 21 C.F.R. §§ 1300-1321.

²³³ See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100; *Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 212 (D.C. Cir. 2017).

distributor has maintained “effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels”; (2) whether the distributor has complied with applicable state and local laws; (3) whether the distributor has previously been convicted under federal or state laws for a crime related to the sale of controlled substances; (4) the distributor's past experience with controlled substances; and (5) “such other factors as may be relevant to and consistent with the public health and safety.”²³⁴

358. Distributors are “one of the key components of the distribution chain” and “must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²³⁵

359. Federal regulations require that Distributor Defendants “shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”²³⁶

360. Distributor Defendants must not ship a suspicious order.²³⁷ Every registrant under the CSA, including the Distributor Defendants, is required to notify the DEA of suspicious orders and stop such orders, thereby ensuring that prescription opioids are not diverted for illegal purposes.

361. The implementing federal regulations provide, “[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious

²³⁴ *Masters Pharm., Inc.*, 861 F.3d at 212 (quoting 21 U.S.C. § 823(b), (e)).

²³⁵ 2006 Rannazzisi letter at 1.

²³⁶ 21 C.F.R. § 1301.71(a). *See also* 21 U.S.C. § 823(b).

²³⁷ *See* Prevoznik, Thomas W., “Distributor Initiative: A National Perspective,” *Dea diversion.usdoj.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, 22 Oct. 2013. Web. 25 Oct. 2017.

orders when discovered by the registrant.”²³⁸

362. The regulations further provides that “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²³⁹ The criteria for suspicious orders:

are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported a suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of the order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the patterns throughout the relevant segment of the regulated industry.²⁴⁰

363. “Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some ‘due diligence’ and – if it is able to determine that the order is not likely to be diverted into illegal channels – ship the order.”²⁴¹

364. Tennessee also places duties on drug distributors. Tennessee law requires that “[e]very person who manufactures, distributes, dispenses, or is a third-party logistics provider for any controlled substance . . . within this state or who proposes to engage in the manufacture, distribution, dispensing, warehousing, or providing logistics services for any controlled substance within this state, shall annually obtain a registration issued by the board of pharmacy and the appropriate occupational or professional licensing board governing persons who may

²³⁸ 21 C.F.R. § 1301.74(b).

²³⁹ *Id.*

²⁴⁰ Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Dec. 27, 2007, at 1 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-8 (D.D.C.)). (hereinafter “2007 Rannazzisi Letter”)

²⁴¹ *Masters Pharm., Inc.*, 861 F.3d at 212–13.

legally dispense controlled substances in accordance with the licensing board's rules.”²⁴²

365. Tennessee law further provides that “[p]ersons registered by the board of pharmacy and the appropriate occupational or professional licensing board governing persons . . . may possess, manufacture, warehouse, distribute, or dispense those substances to the extent authorized by their registration and in conformity with this section.”²⁴³

366. Tennessee law also provides that the state board of pharmacy “shall register an applicant to manufacture or distribute controlled substances . . . unless it determines that the issuance of that registration would be inconsistent with the public interest.”²⁴⁴ One of the factors the Tennessee state board of pharmacy shall consider in determining the public interest is “[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.”²⁴⁵

367. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”²⁴⁶ The guidelines set forth recommended steps in the “due diligence” process, and note in particular “[i]f an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the

²⁴² Tenn. Code Ann. § 53-11-302(a).

²⁴³ *Id.* § 53-11-302(b).

²⁴⁴ *Id.* § 53-11-303(a).

²⁴⁵ *Id.* § 53-11-303(a)(1).

²⁴⁶ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App’x B) (D.C. Cir. Mar. 7, 2012)).

distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.”²⁴⁷

368. The Distributor Defendants sold prescription opioids in and around Shelby County, which Defendants knew were likely to be diverted in Shelby County.

369. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

370. Each Distributor Defendant owes a duty to investigate and refuse suspicious orders of prescription opioids.

371. Each Distributor Defendant owes a duty to report suspicious orders of prescription opioids.

372. Each Distributor Defendant owes a duty to prevent the diversion of prescription opioids into illicit markets in Tennessee and Shelby County.

B. The Distributor Defendants breach their duties and the DEA gets involved

i. The Distributor Defendants failed to report and stop suspicious opioid orders

373. Former DEA agent Joseph Rannazzisi has emphasized the importance of the Distributor Defendants in preventing opioid diversion: “Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . . from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system

²⁴⁷ *Id.*

created by the [Controlled Substances Act] collapses.”²⁴⁸

374. The sheer volume of prescription opioids distributed to pharmacies in Shelby County and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Shelby County, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

375. The Distributor Defendants failed to report suspicious orders originating from Shelby County or which the Distributor Defendants knew were likely to be diverted to Shelby County, to the federal and state authorities, including the DEA and the Tennessee Board of Pharmacy.

376. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Shelby County, and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into Shelby County.

377. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids originating from Shelby County, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Shelby County.

378. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

379. The Distributor Defendants breached their duty to design and operate a system to

²⁴⁸ Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012)).

disclose suspicious orders of controlled substances and failed to inform state and federal authorities of suspicious orders when discovered, in violation of their duties under federal and state law.

380. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

381. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants violated the duties imposed by federal and state law.

382. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and their actions had and continue to have a great probability of causing substantial harm.

383. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

384. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and the subsequent opioid addiction crisis ravaging Tennessee and Shelby County and the damages caused thereby.

ii. The DEA sent warning letters to the Distributor Defendants

385. As a result of the Distributor Defendants' failure to comply with federal law, the DEA has taken a number of actions against them.

386. On September 27, 2006, the DEA sent a letter to "every commercial entity in the

United States registered with the [DEA] to distribute controlled substances.”²⁴⁹

387. The letter stated that manufacturers and distributors “share responsibility for maintaining appropriate safeguards against diversion” and “given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, **even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.**”²⁵⁰

388. The letter advised that “DEA will use its authority to revoke and suspend registrations in appropriate cases.”²⁵¹

389. The letter also provides that “in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”²⁵²

390. The letter further discusses that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²⁵³

391. The DEA sent another letter on December 27, 2007 to “reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders.”²⁵⁴

²⁴⁹ 2006 Rannazzisi Letter at 1.

²⁵⁰ *Id.* at 2 (emphasis added).

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ *Id.* at 1.

²⁵⁴ 2007 Rannazzisi Letter at 1.

392. This letter reminded manufacturers and distributors of their obligation to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”²⁵⁵

393. The letter stated that in terms of reporting suspicious orders:

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”²⁵⁶

394. The 2007 letter also said that “[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant’s DEA Certificate of Registration.”²⁵⁷

395. The 2007 letter also references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which “[i]n addition to discussing the obligation to

²⁵⁵ *Id.*

²⁵⁶ *Id.* at 2.

²⁵⁷ *Id.* at 1-2.

report suspicious orders when discovered” and “some criteria to use when determining whether an order is suspicious,” the order “also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.”²⁵⁸

iii. DEA actions against the Distributor Defendants

396. Under the CSA, the DEA may revoke or suspend an entity’s registration for committing “such acts as would render his registration [under the CSA] inconsistent with the public interest.”²⁵⁹ Typically, before suspending or revoking a registration, the DEA must issue an order to show cause, outlining its basis for the proceedings. However, in instances where the DEA has reason to believe that a registrant’s continued operation would pose “an imminent danger to the public health or safety,” the DEA may suspend the entity’s registration immediately by issuing an Immediate Suspension Order (“ISO”) pursuant to Section 824(d) of the CSA.

397. Because of the Distributor Defendants’ refusal to comply with their legal obligations, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.²⁶⁰ “The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.”²⁶¹

398. **AmerisourceBergen**: On April 24, 2007, the DEA issued an ISO on

²⁵⁸ *Id.* at 2.

²⁵⁹ 21 U.S.C. § 824.

²⁶⁰ “The Drug Enforcement Administration’s Adjudication of Registrant Actions,” *Oig.justice.gov*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014).

²⁶¹ *Id.*

AmerisourceBergen's Orlando, Florida distribution center, alleging that AmerisourceBergen was not controlling shipments of prescription opioids to Internet pharmacies and revoking the facility's license to distribute controlled substances.²⁶²

399. On June 22, 2007, AmerisourceBergen entered into a settlement with the DEA which led to the reinstatement of the Orlando distribution center's suspended license.²⁶³ Under that agreement, AmerisourceBergen was required to implement an enhanced order-monitoring program in all of its distribution centers by June 30, 2007.²⁶⁴

400. In 2012, West Virginia's then-Attorney General Darrell McGraw filed lawsuits against AmerisourceBergen, Cardinal Health, and a dozen smaller drug distributors for their role in a drug supply chain that includes doctors who write prescriptions for nonmedical purposes and "pill mill" pharmacies that dispense excessive numbers of painkillers, including opioids.²⁶⁵ In February 2017, Cardinal Health and AmerisourceBergen agreed to pay \$20 million and \$16 million, respectively, to resolve West Virginia's claims.²⁶⁶

401. The settlement, which is believed to be the largest pharmaceutical settlement in West Virginia history, came shortly after a Charleston Gazette-Mail investigation revealed that drug wholesalers shipped 780 million hydrocodone and oxycodone pills to West Virginia in just six years – a period when 1,728 West Virginians fatally overdosed on those two drugs.²⁶⁷ Cardinal Health and AmerisourceBergen combined to ship nearly 40 percent of all hydrocodone

²⁶² 2007 AmerisourceBergen Corporation Form-10K. Available at: <https://www.sec.gov/Archives/edgar/data/1140859/000119312507255013/d10k.htm>.

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ Eric Eyre, *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail, January 9, 2017. Available at: <http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits>.

²⁶⁶ *Id.*

²⁶⁷ *Id.*

and oxycodone pills to West Virginia.²⁶⁸

402. According to unsealed court documents from the West Virginia case, AmerisourceBergen distributed 149,300 hydrocodone pills – or 12,400 pills a month – to Tug Valley Pharmacy in Mingo County in 2009.²⁶⁹ The pharmacy filled prescriptions for Drs. Diane Shafer, Katherine Hoover and William Rykman, who operated “sham” pain clinics in Williamson.²⁷⁰ Federal agents raided the clinics in 2010 and they never reopened.²⁷¹

403. Unsealed court documents from that case further evidence that AmerisourceBergen shipped 8,000 hydrocodone painkiller tablets to a drive-thru pharmacy over two days in July 2012.²⁷² On those same two days, a competing drug wholesaler shipped 8,600 hydrocodone tablets to the same “pill mill” pharmacy.²⁷³ AmerisourceBergen sold another 3,800 oxycodone pills to same pharmacy that month.²⁷⁴

404. **Cardinal Health**: Based on findings from DEA investigations, in November and December 2007, the DEA issued three ISOs to Cardinal Health.

405. On November 28, 2007, the DEA issued an ISO to Cardinal Health in connection with its distribution center in Auburn, Washington (the “Auburn Facility”), immediately suspending the facility’s Certificate of Registration because its continued registration constituted “an imminent danger to public health and safety.”²⁷⁵

²⁶⁸ *Id.*

²⁶⁹ Eric Eyre, *18 ‘words’ reveal drug giant’s pain pill shipments to WV*, Charleston Gazette-Mail, May 25, 2016. Available at: <http://www.wvgazettemail.com/news/20160525/18-words-reveal-drug-giants-pain-pill-shipments-to-wv>.

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-15 (“Settlement and Release Agreement and Administrative Memorandum of Agreement”), ¶ 2, Appendix B (D.D.C. 2012). (Hereinafter “2008 Cardinal Health MOA”)

406. According to the ISO, the Auburn Facility repeatedly “distributed unusually large amounts of hydrocodone” to Horen’s Drugstore, Inc. (“Horen’s Drugstore”) – distributing 600,000 dosage units of hydrocodone to Horen’s Drugstore from March 2007 through September 2007 – and “disregard[ed] the clear indications that Horen’s Drugstore was engaged in the diversion of controlled substances[.]” Horen’s Drugstore was Cardinal Health’s largest purchaser of combination hydrocodone products in 2007, and according to the ISO, the drugstore was “a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law.” The DEA found that Cardinal Health “failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels,” and concluded that its continued registration with the DEA constituted “an imminent danger to the public health and safety.”

407. On December 5, 2007, the DEA issued an ISO notifying Cardinal Health of the immediate suspension of its Lakeland, Florida drug distribution facility.²⁷⁶

408. The ISO detailed how, from August 2005 through October 2007, Cardinal Health failed to maintain effective controls against the diversion of hydrocodone into other than legitimate medical, scientific and industrial channels. According to the ISO, Cardinal Health distributed hydrocodone to various pharmacies, even though the company knew that many of the orders placed by the pharmacies were of an unusual size and were “suspicious” as defined in the CSA. For example, Cardinal Health distributed 1,213,000 dosage units of hydrocodone to Q-R-G, Inc. over the course of February to June 2006, and approximately 1,148,100 dosage units to

²⁷⁶ 2008 Cardinal Health MOA, ¶ 3, Appendix C.

United Prescription Services, Inc. from July to October 2006. The ISO further detailed that, on September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for Cardinal Health, sent an email to the DEA stating that Cardinal Health discontinued all sales of controlled substances to 13 Internet pharmacies, including RKR Holdings, Inc. Nevertheless, from September 1, 2006 to January 31, 2007, Cardinal Health distributed 393,600 dosage units of hydrocodone products to RKR Holdings.

409. On December 7, 2007, the DEA issued an ISO to Cardinal Health regarding its distribution center in Swedesboro, New Jersey which, from January 2005 to August 2007, “distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.”²⁷⁷

410. The ISO stated that some of Cardinal Health’s “largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice.”

411. In addition to the November and December 2007 ISOs, the DEA issued an Order to Show Cause as to why the agency should not revoke the Certificate of Registration assigned to Cardinal Health’s Stafford, Texas distribution center for the improper distribution of hydrocodone.²⁷⁸ The DEA also found that Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its McDonough, Georgia facility, Valencia, California facility, and Denver, Colorado facility.²⁷⁹ *In total, the DEA had reason to believe that seven of Cardinal Health’s’s twenty-seven then-registered distribution centers were not*

²⁷⁷ *Id.*, ¶ 4, Appendix D.

²⁷⁸ *Id.*, ¶ 5, Appendix E.

²⁷⁹ *Id.*, ¶ 7.

adhering to their obligations under the CSA.

412. Following the three 2007 ISOs and the Order to Show Cause, the DEA and Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (“MOA”) on September 29, 2008.²⁸⁰ Pursuant to the MOA, Cardinal Health agreed to pay a civil fine of \$34 million, and “maintain a compliance program designed to protect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations.”²⁸¹

413. After entry of the 2008 MOA, Cardinal Health began violating the CSA again almost immediately. A further investigation of Cardinal Health’s Lakeland, Florida facility by the DEA “revealed a persistent failure to exercise due diligence to ensure that controlled substances were not being diverted” over a period of approximately 3 years, from November 2008 to December 2011.²⁸² The lack of anti-diversion controls resulted in the top four customers of Cardinal Health’s Lakeland facility being supplied with approximately 50 times the amount of oxycodone compared to the average Florida retailer that Cardinal Health services, which the DEA referred to as a “staggering” difference in distribution.²⁸³

414. The DEA’s further investigation culminated in the issuance of another ISO regarding the Lakeland facility on February 2, 2012 (the “2012 ISO”).²⁸⁴

415. The 2012 ISO stated that, “[d]espite the MOA, the specific guidance to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-2 (“Declaration of Joseph Rannazzisi, Deputy Assistant Administrator for the DEA’s Office of Diversion Control”), ¶ 75 (D.D.C. 2012).

²⁸³ *Id.* ¶ 76.

²⁸⁴ *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-18 (D.D.C. 2012).

substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”²⁸⁵ According to the ISO:

From January 1, 2008 through December 31, 2011 . . . Cardinal’s sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. . . . From 2008 to 2009, Cardinal’s sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal’s sales to its top four retail pharmacy customers increased approximately 162%. [¶] The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal’s Florida retail pharmacies, which receive, on average, approximately 5,347 dosage units of oxycodone per month.²⁸⁶

416. The 2012 ISO further provided that “[n]otwithstanding the large quantities of controlled substances ordered by Cardinal’s top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal’s failure to conduct due diligence of its retail pharmacy chain customers.”²⁸⁷

417. On December 23, 2016, Cardinal Health agreed to pay a \$34 million fine (separate from the \$34 million fine in 2008) to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.²⁸⁸

418. **McKesson:** On May 2, 2008, McKesson agreed to pay a total of \$13.25 million in civil penalties to six U.S. Attorney’s Offices to settle allegations that the company violated federal reporting provisions relating to its handling of prescription painkillers, including

²⁸⁵ *Id.* ¶ 3.

²⁸⁶ *Id.* ¶ 4.

²⁸⁷ *Id.* ¶ 5.

²⁸⁸ Press Release, *United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act*, DOJ, U.S. Attorney’s Office – Middle District of Florida. Available at: <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

hydrocodone.²⁸⁹

419. In a press release regarding the agreement, the Department of Justice explained:

Three McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They did so even after a Sept. 1, 2005, meeting at which DEA officials met with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions. The pharmacies filled purported online “prescriptions” for hydrocodone (contained in drugs such as Vicodin), but the prescriptions were issued outside the normal course of professional practice and not for a legitimate medical purpose. The United States Attorneys allege that the orders that McKesson received from these pharmacies were unusually large, unusually frequent, and/or deviated substantially from the normal pattern. As a result, millions of dosage units of controlled substances were diverted from legitimate channels of distribution.²⁹⁰

420. As part of the 2008 agreement, McKesson was required to “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders . . . and follow procedures established by [McKesson’s] Controlled Substance Monitoring Program (“CSMP”).”²⁹¹ McKesson flagrantly violated those provisions of the agreement.

421. A federal government investigation revealed that, from 2008 to 2013, McKesson did not fully implement its compliance program, and, instead, supplied various U.S. pharmacies

²⁸⁹ Press Release, *McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, Dept. of Justice, May 2, 2008. Available at: <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

²⁹⁰ *Id.*

²⁹¹ 2017 Administrative Memorandum of Agreement (DOJ, DEA and McKesson). Available at: <https://www.justice.gov/opa/press-release/file/928476/download>. (Hereinafter “2017 McKesson MOA”).

an increasing amount of oxycodone and hydrocodone pills.²⁹² For example, in Colorado, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious.²⁹³

422. When confronted with the evidence gathered in the government's investigation, McKesson conceded that, following the 2008 agreement, the company:

- “[F]ailed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA . . . at the McKesson Distribution Centers” located in: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs California; Washington Courthouse, Ohio; and West Sacramento, California;²⁹⁴
- “[F]ailed to properly monitor its sales of all controlled substances and report suspicious orders to DEA, in accordance with McKesson’s obligations under the 2008 Agreements”;²⁹⁵
- “[F]ailed to conduct due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious reporting procedures set forth in the McKesson CSMP”;²⁹⁶
- “[F]ailed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency”;²⁹⁷

²⁹² Press Release, *McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, Dept. of Justice, January 17, 2017. Available at: <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

²⁹³ *Id.*

²⁹⁴ 2017 McKesson MOA at 3.

²⁹⁵ *Id.* at 4.

²⁹⁶ *Id.*

²⁹⁷ *Id.*

- “[F]ailed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters”;²⁹⁸ and
- “[D]istributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners in the usual course of their professional practice.”²⁹⁹

423. Following the federal government’s investigation, in January 2017, McKesson entered into an Administrative Memorandum of Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 agreement as well as failure to identify and report suspicious orders of controlled substances at its drug distribution centers across the country.³⁰⁰ The 2017 agreement further required McKesson to suspend sales of controlled substances from its distribution centers in Colorado, Ohio, Michigan and Florida for multiple years.³⁰¹ The suspensions are among the most severe sanctions ever agreed to by a DEA registered distributor.

iv. The Distributor Defendants misled the public concerning their duties and compliance

424. In *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration* (D.C. Cir), the Healthcare Distribution Management Association (“HDMA”) – a trade association run by the Distributor Defendants, and National Association of Chain Drug Stores (“NACDS”) submitted

²⁹⁸ *Id.*

²⁹⁹ *Id.*

³⁰⁰ 2017 McKesson MOA at 8.

³⁰¹ *Id.* at 5 – 7.

briefs regarding the legal duty of wholesale distributors.³⁰² Their briefs inaccurately denied the legal duties that Distributor Defendants have failed to fulfill. For example

- The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³⁰³
- The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. 80 Fed. Reg. at 55,421, 55,475-77, 55,479. Such a change in agency position must be accompanied by an acknowledgement of the change and a reasoned explanation for it. In other words, an agency must “display awareness that it is changing position” and “show that there are good reasons for the new policy.” *Fox Television Stations, Inc.*, 556 U.S. at 515. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.”³⁰⁴
- The Associations alleged “Section 1301.71 by its terms restricts DEA’s authority to delineate the requirements for “effective controls” – stating that, in evaluating a control system, the Administrator “shall use the security requirements set forth in §§ 1301.72-1301.76.” 21 C.F.R. § 1301.71(a) (emphasis added). Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³⁰⁵
- The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has

³⁰² The HDMA – now known as the Healthcare Distribution Alliance (“HAD”) – is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen, Cardinal Health, and McKesson. *See generally* HDA, About, <https://www.healthcaredistribution.org/about>. The NACDS is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, Mission, <https://www.nacds.org/about/mission/>.

³⁰³ Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf’t Admin.*, USCA Case #15-1335, Doc. No. 1607110, at 4–5 (D.C. Cir. Apr. 4, 2016).

³⁰⁴ *Id.* at 8.

³⁰⁵ *Id.* at 14.

complied with the APA before attempting to impose such duties.”³⁰⁶

- The Associations alleged (inaccurately) that “DEA’s regulations had sensibly imposed a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³⁰⁷
- Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”³⁰⁸

425. Rejecting the Associations’ contentions, the United States Court of Appeals for the District of Columbia issued an opinion stating that “[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and – if it is able to determine that the order is not likely to be diverted into illegal channels – ship the order (the Shipping Requirement).”³⁰⁹

426. The Distributor Defendants have also undertaken to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

427. For example, a Cardinal Health executive said the company “deploys ‘advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.’”³¹⁰

428. Given the sales volumes and the company’s history of violations, this executive

³⁰⁶ *Id.* at 22.

³⁰⁷ *Id.* at 24-25.

³⁰⁸ *Id.* at 26.

³⁰⁹ *Masters Pharm., Inc.*, 861 F.3d at 212–13.

³¹⁰ Bernstein, Lenny et al., “How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: ‘No one was doing their job,’” *The Washington Post*, 22 Oct. 2016.

was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

429. Similarly, McKesson publicly stated that it has “put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain,” and “[o]ur team is deeply passionate about curbing the opioid epidemic in our country.”³¹¹

430. Given McKesson’s past conduct, this statement is either false, or the company ignored the results of its monitoring program.

431. Rather than abide by their duties, the Distributor Defendants and their association, the Healthcare Distribution Alliance, spent \$13 million to lobby House and Senate members and their staff in favor of legislation called “Ensuring Patient Access and Effective Drug Enforcement Act” which, as one article described, “raises the standard for the diversion office to obtain an immediate suspension order. Now the DEA must show an “immediate” rather than an “imminent” threat to the public, a nearly impossible burden to meet against distributors, according to former DEA supervisors and other critics. They said the new law gives the industry something it has desperately sought: protection from having its drugs locked up with little notice.”³¹² After an explosive media report on the Distributor Defendants’ lobbying effort, the Congressman who sponsored the bill and who was slated to be the President’s new Drug Czar, withdrew his name from consideration.

432. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts giving rise to the claims that Shelby County now asserts.

³¹¹ Higham, Scott et al., “Drug Industry Hired Dozens of Officials from the DEA as the Agency tried to Curb Opioid Abuse,” *The Washington Post*, 22 Dec. 2016.

³¹² Bernstein, Lenny et al., “Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control,” *The Washington Post*, 22 Oct. 2016.

433. In September 2017, 41 state Attorneys General served opioid manufacturers and distributors with subpoenas and document requests seeking information concerning how the companies marketed and distributed opioids.³¹³

434. Meanwhile, the opioid epidemic ravages Shelby County because the fines and suspensions imposed by the DEA did not change the conduct of Distributor Defendants. The Distributor Defendants simply pay fines as a cost of doing business in their industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

435. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and allowed diversion in Tennessee and Shelby County for their economic benefit.

VI. Tennessee's epidemic of opioid overdoses and Neonatal Abstinence Syndrome

A. Tennessee and Shelby County are flooded with prescription opioids, resulting in a surge in opioid overdose deaths and significant collateral damage

436. According to the Tennessee Department of Health's Drug Overdose Dashboard, there were **7,636,112 opioid prescriptions** written in Tennessee in 2016 alone.³¹⁴ That is a rate of **1,148 opioid prescriptions per 1,000 people**.³¹⁵ Tennessee has been called out as having the second highest statewide opioid prescription rate in the nation.³¹⁶

³¹³ Press Release, "A.G. Schneiderman, Bipartisan Coalition Of AGs Expand Multistate Investigation Into Opioid Crisis," *New York State Office of the Attorney General*, 19 Sept. 2017.

³¹⁴ Tennessee Drug Overdose Dashboard. Available at: <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

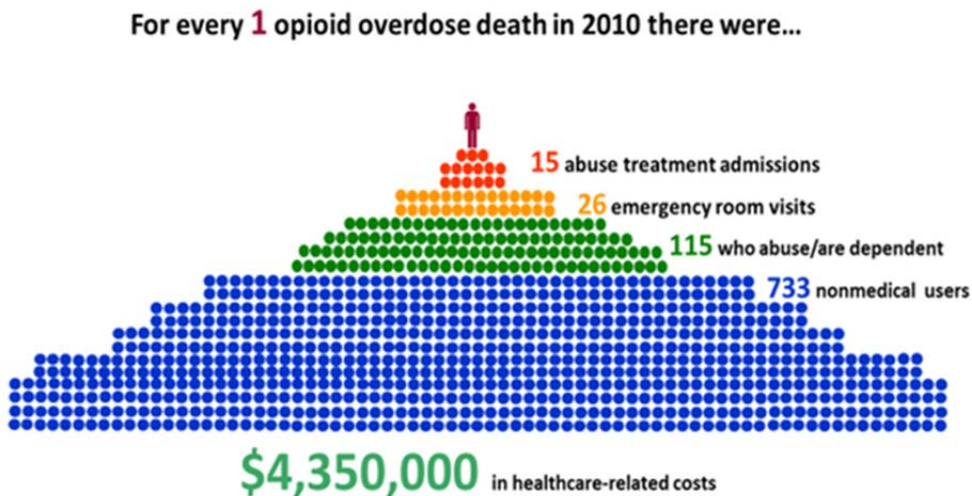
³¹⁵ *Id.*

³¹⁶ Rodney L. Bragg, Assistant Commissioner, Tennessee Department of Mental Health and Substance Abuse Services, "Prescription Drug Epidemic in Tennessee," May 22, 2014 (citing CDC, MMWR weekly: Vital signs: overdose of prescription pain relievers – United States, 1999-2008).

437. Tennessee also saw a record high 1,186 opioid overdose deaths in 2016, which equates to more than 3 overdose deaths every single day.³¹⁷

438. Between 2005 and 2015, just one decade, unintentional overdose deaths in Tennessee increased over 250%.³¹⁸ Unintentional overdose deaths now account for more early deaths in Tennessee than automobile accidents, suicides, or homicides.³¹⁹

439. Opioid overdose deaths represent the “tip of the iceberg” of the human and societal costs of the opioid epidemic:³²⁰



440. In Shelby County, there were **674,033 opioid prescriptions** written in 2016 alone.³²¹ That is a rate of **721 opioid prescriptions per 1,000 people**.³²²

441. Between 2012 and 2016, there were a staggering 570 opioid overdose deaths in

³¹⁷ *Id.*

³¹⁸ *Working Group Report* at 3 (citing Tenn. Dep’t of Health Chronic Pain Guidelines).

³¹⁹ *Working Group Report* at 3 (citing Tenn. Dep’t of Health Chronic Pain Guidelines).

³²⁰ Benjamin Schachtman, ‘Closer to Home’ – The Cost of the Opioid Epidemic May be the Tip of the Iceberg, portcitydaily.com, Apr. 3, 2017 (attributing graphic chart to the N.C. Public Health Department). Available at: <http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/>.

³²¹ Tennessee Drug Overdose Dashboard. Available at: <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

³²² *Id.*

Shelby County, 150 of which occurred in 2016 alone.³²³ In 2016, the opioid overdose death rate in Shelby County was 16 overdose deaths per 100,000 people.³²⁴ To put that number in context, the rate for people who died in car crashes in Tennessee in 2015 was only 14.7 per 100,000 people.³²⁵

442. Overdose deaths related to heroin in Shelby County rose 883 percent between 2011 (9 cases) and 2014 (84 cases).³²⁶ There was also an increase in heroin-related arrests in the area. The number of people arrested for heroin-related crimes (per 10k population) was 5 to 7 times higher in Shelby County in 2015-2016 than that same rate in 2009-2010.³²⁷

443. In addition to the high rates of overdose death, in Shelby County the total outpatient hospital visits involving all *nonfatal* overdoses increased 124% between 2012 (1,191 total outpatient visits) and 2015 (1,477 total outpatient visits).³²⁸ Outpatient visits related to nonfatal heroin overdose accounted for approximately 11.8% of the total in 2015.³²⁹ The number of inpatient hospital visits involving nonfatal heroin overdoses also increased nearly twofold during that timeframe (22 total inpatient visits in 2012 compared to 42 total inpatient visits in 2015).³³⁰

³²³ *Id.*

³²⁴ *Id.*

³²⁵ Nate Morabito, *Drug overdoses in Tennessee set tragic record*, wjhl.com. Available at: <http://wjhl.com/2016/11/15/drug-overdoses-in-tennessee-set-tragic-record/>.

³²⁶ Ryan Pope, *Tennessee, Shelby County look to sue as opioid costs mount*, USA Today Network, June 10, 2017. Available at: <http://www.commercialappeal.com/story/news/government/county/2017/06/11/tennessee-shelby-county-look-sue-opioid-costs-mount/383687001/>.

³²⁷ https://www.tn.gov/assets/entities/behavioral-health/p-r-f/attachments/Heroin_Indicators_3.15.2017.pdf (last visited Oct. 11, 2017).

³²⁸ Tennessee Department of Health's Drug Overdose Data Dashboard/ Available at: <http://tn.gov/health/topic/pdo-data-dashboard>.

³²⁹ *Id.*

³³⁰ *Id.*

B. Tennessee’s epidemic of Neonatal Abstinence Syndrome (“NAS”) – a condition suffered by babies of mothers addicted to opioids

444. NAS is a clinical diagnosis, and “a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.”³³¹

445. According to a report produced by Governor Bill Haslam’s Opioid Abuse Working Group (“Governor’s Working Group Report”), “[t]he number of babies born with Neonatal Abstinence Syndrome (NAS) . . . increased tenfold from 2000 to 2010.”³³² Since 2010, the problem has only gotten worse.

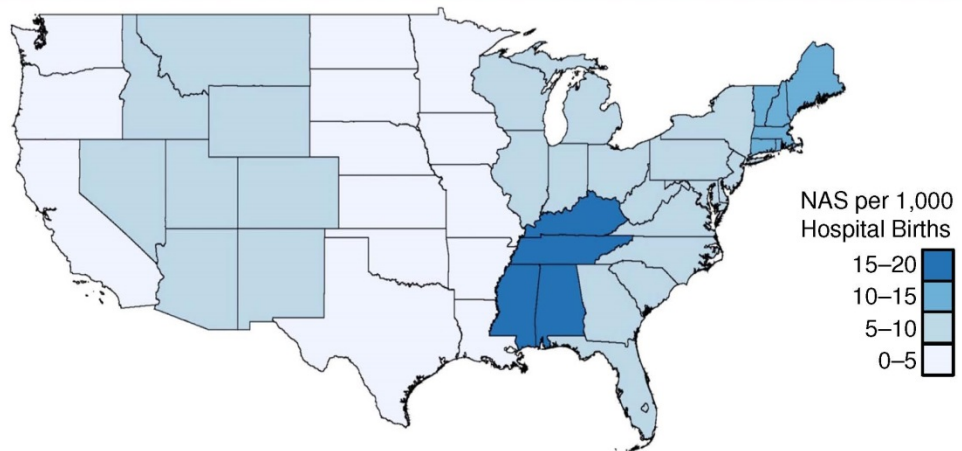
446. As illustrated by the following map, researchers analyzing hospital discharge data have determined that Tennessee, along with its border states Kentucky, Alabama, and Mississippi, have the highest rates of NAS births in the nation.³³³

³³¹ Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) *Pediatrics* 547, 547-48 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf>.

³³² Opioid Abuse Reduction Act Working Group, Tenn. Dep’t of Mental Health and Substance Abuse Services, *Working Group Report* 4 (2015) [hereinafter *Working Group Report*].

³³³ Stephen W. Patrick et al., *Increasing Incidence of Neonatal Abstinence Syndrome: United States 2009-2012*, 35(8) *J. Perinatol.* 650, 650-55.

NAS Incidence by Geographic Region, 2012



Patrick SW, Davis MM, Lehmann CU, et al. *J Perinatol.* 2015 Aug;35(8):650-5.

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447. The percentage of pregnant women served by the Tennessee Department of Mental Health & Substance Abuse Services listing prescription opioids as their primary substance of abuse – 42.3% in 2012 – was over twice the percentage in the United States overall (18.4% in 2012).

448. In 2015, there were approximately 2.6 cases of NAS per 1,000 live births in Shelby County.³³⁴

³³⁴ https://www.tn.gov/assets/entities/health/attachments/Dec_2015_NAS_Monthly_Report.pdf (last visited Oct. 11, 2017).

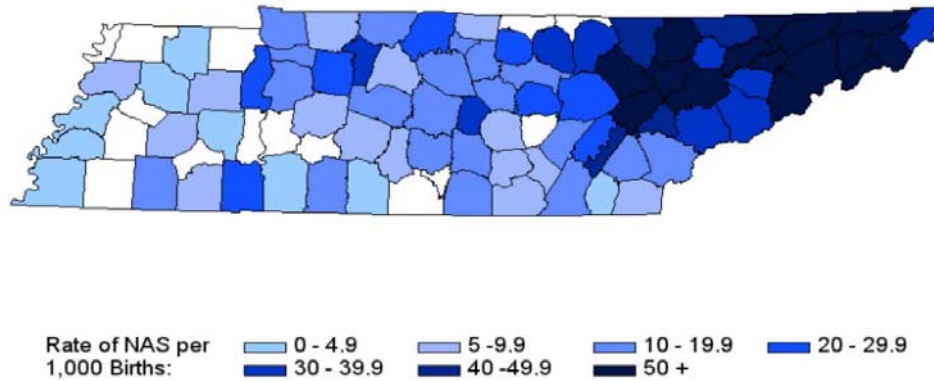


Figure 198. Incidence of NAS among TennCare recipients, 2014

Source: Bureau of TennCare Division of Health Care Finance and Administration (Provisional Data)

449. TennCare eligibility records establish that 24.3% of babies born with NAS in 2012 were placed in the Department of Children’s Services’ custody within one year of birth.³³⁵

450. The epidemic of NAS babies is an outgrowth of the explosion in the amount of opioids in Tennessee since the mid-1990s.

451. The direct link between the Producer Defendants’ fraudulent campaign to flood America with opioids and the NAS baby crisis in Tennessee has been clearly stated by Tennessee’s Commissioner of Health Dr. John Dreyzehner. In a 2015 presentation entitled “Neonatal Abstinence Syndrome: A Tennessee Perspective,” Commissioner Dreyzehner addressed **“the Substance Abuse Epidemic and resulting NAS epidemic.”**³³⁶

452. In his NAS presentation, Commissioner Dreyzehner identified the obvious link between opioid sales and opioid related health problems, noting “the incredible correlation between sales and supply and availability [of opioids] and opioid related deaths and opioid treatment admissions.”³³⁷

453. The following two charts from the Tennessee Health Department show the close

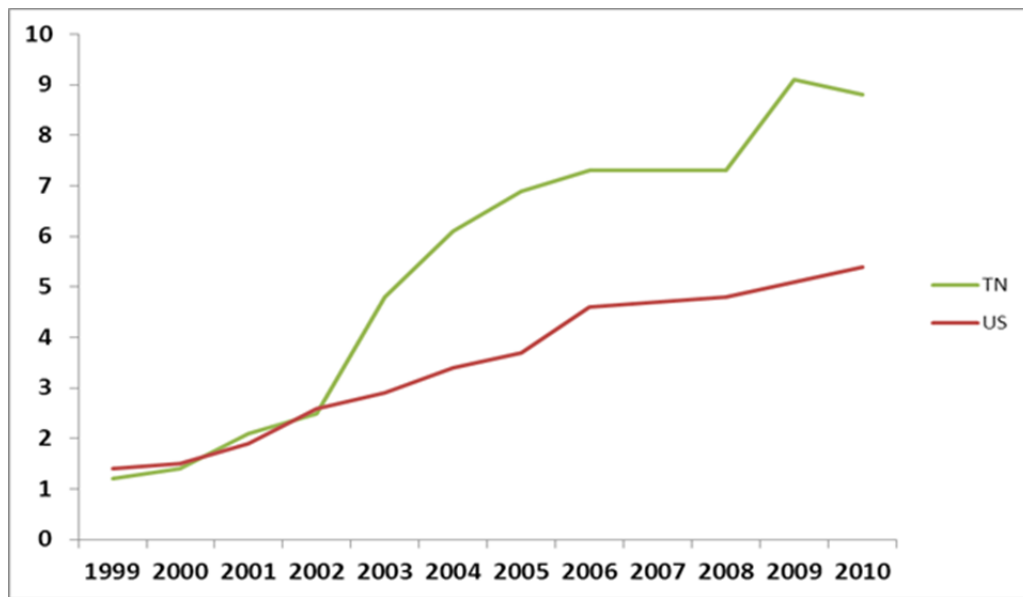
³³⁵ *Working Group Report* at 4.

³³⁶ National DEC, “Neonatal Abstinence Syndrome A Tennessee Perspective,” Vimeo, May 4, 2015. Available at: <https://vimeo.com/126839454>.

³³⁷ *Id.*

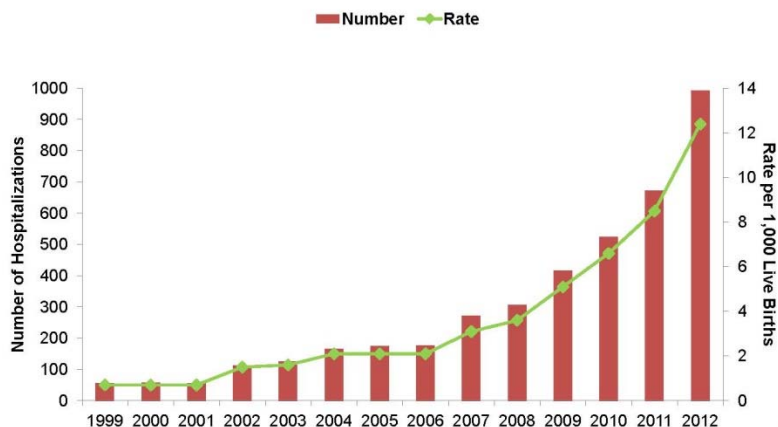
correlation between skyrocketing Tennessee opioid overdoses and the increase in Tennessee babies suffering from NAS:

**Rates of Opioid-Related Overdose Death (rate per 100,000 population)
Tennessee and United States, 1999-2010**



Source: Tennessee Department of Health – Vital Statistics.

**NAS Hospitalizations in TN:
1999-2012**



Data sources: Tennessee Department of Health; Office of Health Statistics; Hospital Discharge Data System (HDDS) and Birth Statistical System. Analysis includes inpatient hospitalizations with age less than 1 and any diagnosis of drug withdrawal syndrome of newborn (ICD-9-CM 779.5). HDDS records may contain up to 18 diagnoses. Infants were included if any of these diagnosis fields were coded 779.5.



454. As Dr. Stephen Loyd, Medical Director of the Tennessee Department of Mental Health and Substance Abuse Services, recently testified before the Tennessee House of Representatives' Opioid Task Force ("House Opioid Task Force"): "[m]arketing of opioids as having a low addictive potential when used for the treatment of chronic pain" resulted in "opioids prescribed more freely by practitioners," and, in turn, an "increase in number of babies born drug dependent."³³⁸

455. As direct and proximate result of the Defendants' acts and omissions, the Plaintiff has sustained economic damages, including but not limited to increased costs associated with law enforcement, health care, public education, drug treatment, and other damages to be established through discovery and trial.

TOLLING AND FRAUDULENT CONCEALMENT

456. Plaintiff Shelby County continues to suffer harm from the unlawful actions by the Defendants.

457. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

458. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assured the public, including Tennesseans and Shelby County residents, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status

³³⁸ House Opioid Task Force, February 23, 2017.

in the State and to continue generating profits. The Defendants affirmatively assured the public, including Tennessee and Shelby County, that they were working to curb the opioid epidemic.

459. The Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further publicly affirmed that their conduct was in compliance with those obligations.

460. The Distributor Defendants have also concealed and prevented discovery of information that will confirm the extent of their wrongful and illegal activities.

461. The Producer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Producer Defendants invented the term “pseudoaddiction” and promoted it to an unsuspecting medical community. Producer Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Producer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Producer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales. Producer Defendants also intentionally aimed their products to patients for uses not approved by the FDA in order to bolster demand for their products. The medical community, consumers, Tennessee, and Shelby County were duped by the Producer Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Shelby County.

462. Plaintiff Shelby County reasonably relied on Defendants’ affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

463. Plaintiff Shelby County’s claims are equitably tolled because Defendants

knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from the Plaintiff. Plaintiff Shelby County did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

464. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where Plaintiff Shelby County filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

465. In light of their statements to the media, in legal filings, and settlements, Defendants had actual and constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

466. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff Shelby County was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on their part.

CAUSES OF ACTION

COUNT I:

TENNESSEE'S DRUG DEALER LIABILITY ACT ("DDLA")

(Tenn. Code Ann. § 29-38-101, *et seq.*)

467. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

468. Tennessee's DDLA, Tenn. Code Ann. § 29-38-101 *et seq.*, provides a civil remedy for "damages to persons in a community as a result of illegal drug use." Tenn. Code Ann. § 29-38-102.

469. Among the persons to whom the DDLA provides a remedy are “[a] medical facility, insurer, governmental entity, employer, or other entity that funds a drug treatment program or employee assistance program for the individual drug user, or that otherwise expended money on behalf of the individual drug user.” Tenn. Code Ann. § 29-38-106.

470. Plaintiff is a governmental entity that funds drug treatment and assistance programs for individual drug users in Shelby County, and otherwise expended significant sums of money as a result of the illegal distribution of prescription opioids in Shelby County.

471. The DDLA makes anyone who “knowingly participates in the illegal drug market within this state ... liable for civil damages.” Tenn. Code Ann. § 29-38-105(a).

472. “A person may recover damages under [the DDLA] ... for injury resulting from an individual’s use of an illegal drug.” Tenn. Code Ann. § 29-38-105(b).

473. Under Tennessee criminal laws, such as Tenn. Code Ann § 39-17-417 and Tenn. Code Ann § 39-17-418, hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, Opana, Lortab, Fentanyl and other opioids are illegal drugs if possessed, sold, and distributed without a valid prescription.

474. The DDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damages. Damages may be recovered under the DDLA from a “person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user.” Tenn. Code Ann. § 29-38-106(5)(b)(1).

475. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages. Damages may be recovered under the DDLA from a “person who knowingly participated in the illegal drug market, if (A)

[t]he place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) the defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he defendant participated in the illegal drug market at any time during the individual user's period of illegal drug use." Tenn. Code Ann. § 29-38-106(5)(b)(2)(A)-(C).

476. For purposes of the DDLA, an "'individual drug user' means the individual whose illegal drug use is the basis of an action brought under [that statute]," Tenn. Code Ann. § 29-38-104(4).

477. Residents of Shelby County who acquired prescription opioids from unlicensed drug dealers illegally distributing the opioids in Shelby County are "individual drug user[s]" under the DDLA.

478. Those purchases of prescription opioids were illegal in that they were made without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).

479. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached Shelby County during all times relevant to this complaint. For purposes of the DDLA, Defendants' "illegal drug market target community" is the entire state of Tennessee, because Defendants participated in the illegal drug market by distributing 4 ounces or more of a "specified illegal drug." Tenn. Code Ann §§ 29-38-104(8), 29-38-109(4). As noted by the Tennessee Department of Health in a 2015 presentation, the Tennessee market for hydrocodone and oxycodone pills comprised of 51 hydrocodone pills and 21 oxycodone pills for every Tennessean. Commissioner of Health Dreyzehner noted that 50% of mothers of NAS babies obtained their pills, in whole or in part, from diverted pills (28.7% solely from diverted drugs). Given that a single oxycodone tablet, on information and belief, weighs approximately

135 mg and contains at least 10 mg of opioid, there can be no question that each of the Defendants far exceeded the four-ounce level.

480. Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

481. As a result, Defendants knowingly disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including “pill mills.”

482. Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, knowing that such opioids would be illegally trafficked and abused.

483. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Plaintiff Shelby County.

484. Having knowingly participated in the illegal distribution of prescription opioids, the drugs purchased by residents of Shelby County in the “place of illegal drug activity,” Defendants are liable to Plaintiff Shelby County under the DDLA even for damages caused by opioids in Shelby County that were acquired from distribution channels in which Defendants were not a market participant.

**COUNT II:
PUBLIC NUISANCE
(Tennessee Common Law)**

485. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

486. Under Tennessee common law, a “public nuisance” is defined as any “condition of things which is prejudicial to health, comfort, safety, property, sense of decency or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law.” *State ex rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975). A common law nuisance “extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable or comfortable use of property.” *Id.*

487. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Shelby County for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

488. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Plaintiff Shelby County and its residents.

489. The Producer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

- The Producer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Shelby County.
- The Producer Defendants’ actions created and expanded the market for opioids, promoting its wide use for pain management.
- The Producer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the

serious adverse effects of opioids, including the addictive nature of the drug.

- The Producer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

490. The Producer Defendants' actions were a substantial factor in opioids becoming widely available and widely used. The Producer Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain.

491. The Distributor Defendants each breached their duty to report and stop suspicious orders of prescription opioids.

492. Without the Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

493. Defendants' nuisance-causing activities include illegally selling, or facilitating the illegal sale of, prescription opioids from premises in and around Shelby County to unintended users in Shelby County – including people at risk of overdose and criminals.

494. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion, and misuse of prescription opioids, and their failure to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

495. Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the

black market, including pill mills and other dealers.

496. Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

497. The public nuisance created by Defendants endangers the health and safety of Shelby County and its residents.

498. The public nuisance created by Defendants has caused, and continues to cause, significant harm to Shelby County including, but not limited to:

- The staggering rates of opioid use among adults in Shelby County has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Shelby County.
- Infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- The Producer Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Producer Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.
- The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the

medical, public health, law enforcement, and financial resources of Shelby County.

- Adults and children in Shelby County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

499. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resource which could be used to benefit the public at large in Shelby County.

500. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Producer Defendants' dissemination of false "scientific" facts and advice.

501. At all times, Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the surrounding Shelby County. Defendants had the power to shut off the supply of illicit opioids into Shelby County. The Producer Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. As a direct and proximate result of the public nuisance, Shelby County has sustained harm by spending a substantial amount of money trying to fix the societal harms caused by the

Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, and law enforcement.

502. Defendants should be required to pay the expenses Plaintiff Shelby County has incurred or will incur in the future to fully abate the nuisance.

**COUNT III:
PUBLIC NUISANCE
(Tenn. Code Ann. § 29-3-101, *et seq.*)**

503. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

504. Under Tennessee statutory law, “[a]ny person who uses, occupies, establishes or conducts a nuisance, or aids or abets therein, and the owner, agent or lessee of any interest in any such nuisance, together with the persons employed in or in control of any such nuisance by any such owner, agent or lessee, is guilty of maintaining a nuisance and such nuisance shall be abated as provided hereinafter.” Tenn. Code Ann. § 29-3-101(b).

505. The term “nuisance” includes “[a]ny place in or upon which . . . [the] unlawful sale of any regulated legend drug, narcotic or other controlled substance . . . are carried on or permitted, and personal property, contents, furniture, fixtures, equipment and stock used in or in connection with the conducting and maintaining any such place for any such purposes.” *Id.* § 29-3-101(a)(2)(A).

506. Illegal opioids produced and distributed by Defendants are being used, exchanged, and sold in parking lots, drug houses, back alleys and pill mills throughout Shelby County.

507. The nuisance statute further provides that, in an “order of abatement, the court may . . . assess costs of public services required to abate or manage the nuisance, including, but not limited to, law enforcement costs, if any, caused by the public nuisance.” *Id.* § 29-3-110.

508. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Plaintiff Shelby County.

509. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Shelby County for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

510. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Plaintiff Shelby County and its residents.

511. The Producer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

- The Producer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Shelby County.
- The Producer Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.
- The Producer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drug.
- The Producer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

512. The Producer Defendants' actions were a substantial factor in opioids becoming

widely available and widely used. The Producer Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain.

513. The Distributor Defendants each breached their duty to report and stop suspicious orders of prescription opioids.

514. Without the Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

515. Defendants' nuisance-causing activities include illegally selling, or facilitating the illegal sale of, prescription opioids from premises in and around Shelby County to unintended users in Shelby County – including people at risk of overdose and criminals.

516. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and their failure to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

517. Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including pill mills and other dealers.

518. Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

519. The public nuisance created by Defendants endangers the health and safety of Shelby County and its residents.

520. The public nuisance created by Defendants has caused, and continues to cause, significant harm to Shelby County including, but not limited to:

- The staggering rates of opioid use among adults in Shelby County has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Shelby County.
- Infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- The Producer Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Producer Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.
- The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Shelby County.
- Adults and children in Shelby County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages,

or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

521. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resource which could be used to benefit the public at large in Shelby County.

522. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Producer Defendants' dissemination of false "scientific" facts and advice.

523. At all times, Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the surrounding Shelby County. Defendants had the power to shut off the supply of illicit opioids into Shelby County. The Producer Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. As a direct and proximate result of the public nuisance, Shelby County has sustained harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, and law enforcement.

524. Defendants should be required to pay the expenses Plaintiff Shelby County has incurred or will incur in the future to fully abate the nuisance.

**COUNT IV:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO")
(18 U.S.C. § 1961, *et seq.*)**

525. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

526. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise or a legal entity enterprise. At all relevant times, the Defendants were “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

527. Section 1962(c) of RICO makes it unlawful “for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

528. The term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. United States*, 556 U.S. 938, 944 (2009); *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 853 (7th Cir. 2013). The definition of “enterprise” in Section 1961(4) includes both legitimate and illegitimate enterprises. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ – the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’” *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

529. For over a decade, the Defendants aggressively sought to bolster their revenue,

increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

530. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market “by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”³³⁹

531. Defendants’ illegal scheme was implemented by an association-in-fact enterprise between the Producer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants’ scheme allowed them to make

³³⁹ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, *Drugcaucus.senate.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, Before the Caucus on International Narcotics Control, United States Senate, 5 May 2015. (hereinafter “Rannazzisi May 5, 2015 Testimony”).

billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Shelby County suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

532. In addition, or in the alternative, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")³⁴⁰ is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

533. Each of the Defendants is a legal entity separate and distinct from the HDA. Further, the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

³⁴⁰ Health Distribution Alliance, *History*, Health Distribution Alliance, <https://www.healthcaredistribution.org/about/hda-history>.

534. The legal and association-in-fact enterprises were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

535. **The Opioid Diversion Enterprise**: In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.³⁴¹ The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to know their customers.³⁴²

536. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”³⁴³

537. When evaluating production quotas, the DEA was instructed to consider the following information:

- Information provided by the Department of Health and Human Services;
- Total net disposal of the basic class by all manufacturers;
- Trends in the national rate of disposal of the basic class;

³⁴¹ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Sept. 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Dec. 27, 2007).

³⁴² See “Suggested Questions a Distributor should ask prior to Shipping Controlled Substances, *Deaiversion.usdoj.gov*/, U.S. Dept. of Justice, Drug Enforcement Administration.

³⁴³ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Rannazzisi May 5, 2015 Testimony.

- An applicant's production cycle and current inventory position;
- Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.³⁴⁴

538. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.³⁴⁵

539. At all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

540. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its

³⁴⁴ Rannazzisi May 5, 2015 Testimony at 3.

³⁴⁵ *Id.* at 4 (citing 21 U.S.C. § 842(b)).

purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

541. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum ("PCF"), described in greater detail below, and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.³⁴⁶ The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

542. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent

³⁴⁶ See "HDMA is now the Healthcare Distribution Alliance," *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016.; Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016.; Higham, Scott et al., "U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis," *The Washington Post*, 6 Mar. 2017.; Eyre, Eric, "DEA Agent: 'We Had no Leadership' in West Virginia Amid Flood of Pain Pills," *100daysinappalachia.com/*.

scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

543. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout Shelby County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

544. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

545. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and

management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

546. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF, the HDA, and through their contractual relationships.

547. The PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

548. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”³⁴⁷ Specifically, PCF participants spent over \$740 million lobbying in the nation’s capital and in all 50 state houses on an array of issues, including opioid-related measures.”³⁴⁸

549. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.³⁴⁹ In 2012, membership and participating organizations included the HDA (of which all Defendants are

³⁴⁷ Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016.

³⁴⁸ *Id.*

³⁴⁹ PAIN CARE FORUM 2012 Meetings Schedule, <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Scheduleamp.pdf>, last updated Dec. 2011.

members), Endo, Purdue, Janssen, and Cephalon.³⁵⁰ Each of the Producer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Producer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.³⁵¹

550. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

551. Second, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Producer Defendants are members.³⁵² And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Producer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

552. In fact, the HDA touted the benefits of membership to the Producer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working

³⁵⁰ *Id.*

³⁵¹ *Id.*

³⁵² “Manufacturer Membership,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

groups with peers and trading partners,” and “make connections.”³⁵³ The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

553. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants.³⁵⁴ The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

554. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks.³⁵⁵

555. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

556. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Producer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing

³⁵³ “Manufacturer Membership Benefits,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³⁵⁴ “Manufacturer Membership Application Instructions,” *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web

³⁵⁵ “Councils and Committees,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

industry issues.”³⁵⁶ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”³⁵⁷ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Producer Defendants embraced this opportunity by attending and sponsoring these events.³⁵⁸

557. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

558. The Producer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Producer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Producer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.³⁵⁹ The Producer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

³⁵⁶ “Business and Leadership Conference – Information for Manufacturers,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³⁵⁷ *Id.*

³⁵⁸ See “2015 Distribution Management Conference and Expo,” Healthcare Distribution Alliance, *Healthcaredistribution.org*, Healthcare Distribution Alliance.

³⁵⁹ See “Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

559. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

560. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

561. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for “more than a decade.”³⁶⁰ Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.³⁶¹

562. As described above, the Defendants began working together as early as 2006 through the PCF and the HDA to promote the common purpose of their enterprise. Defendants worked together as an ongoing and continuous organization throughout the existence of their

³⁶⁰ Perrone, Matthew, “Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic,” *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016.

³⁶¹ “History,” *Healthcaredistribution.org*, Healthcare Distribution Alliance.

enterprise.

563. **Conduct of the Opioid Diversion Enterprise:** During the time period alleged in this complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

564. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

565. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

566. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

567. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. The Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

568. The Defendants exercised control and influence over the distribution industry by

participating and maintaining membership in the HDA.

569. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”

570. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Producer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. The Producer Defendants also used this high-level information to direct the Distributor Defendants’ sales efforts to regions where prescription opioids were selling in larger volumes.

571. The Producer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Producer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

572. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.³⁶² The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities,

³⁶² See Widup, Richard et al., “*Pharmaceutical Production Diversion: Beyond the PDMA*,” *Mcguirewoods.com*.

and cancer treatment facilities, and these questionnaires also put the recipients on notice of suspicious orders.

573. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.

574. The Defendants' scheme had decision-making structure that was driven by the Producer Defendants and corroborated by the Distributor Defendants. The Producer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

575. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

576. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for

decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

- The Distributor Defendants assisted the enterprise and the Producer Defendants in their lobbying efforts through the PCF;
- The Distributor Defendants invited the participation, oversight and control of the Producer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- The Distributor Defendants provided sales information to the Producer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- The Producer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- The Producer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids].";
- The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- The Producer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- The Defendants identified suspicious orders of prescription opioids and

then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

- The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the “medical need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

577. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

578. **Pattern of Racketeering Activity**: The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

579. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Tennessee and Shelby County, by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through

a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

580. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

581. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

582. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

583. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

584. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Producer Defendants, Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- The prescription opioids themselves;
- Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- The Defendants' DEA registrations;
- Documents and communications that supported and facilitated the Defendants' DEA registrations;
- Documents and communications that supported and facilitated the

Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

- The Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- Documents for processing and receiving payment for prescription opioids;
- Payments from the Distributor Defendants to the Producer Defendants;
- Rebates and chargebacks from the Producer Defendants to the Distributor Defendants;
- Payments to the Defendants' lobbyists through the PCF;
- Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- Other documents and things, including electronic communications.

585. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

586. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

587. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

588. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

589. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

590. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion Enterprise's operation and goals, including false and misleading certifications required annually under the following:

- Section V.j of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);
- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);
- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and
- Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

591. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

592. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include

thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

593. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

594. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

595. The Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

596. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

597. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

598. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly

addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

599. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to its business and property through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

600. The pattern of racketeering activity and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

601. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

602. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

603. Each instance of racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiff, its residents, and its community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the

pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

604. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

605. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

606. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

607. **The RICO Defendants manufactured, sold, and/or dealt in controlled substances and their crimes are punishable as felonies:** The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

608. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material

information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

609. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

610. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

611. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the Producer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

612. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized in January 2017.

613. Purdue's experience with the organized drug ring in Los Angeles, which Purdue knew about but failed to report to the DEA, is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids.

614. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.

615. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.

616. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

617. Many of the precise dates of Defendants' criminal actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

618. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar

results affecting similar victims, including Plaintiff, its residents, and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

619. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

620. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

621. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

622. **Damages:** The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic.

623. Plaintiff's injuries, and those of their residents and community, were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

624. Plaintiff's injuries and those of its residents and community were directly caused

by the Defendants' racketeering activities.

625. Plaintiff was most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

626. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of this lawsuit and pre- and post-judgment interest.

**COUNT V:
RICO CONSPIRACY
(18 U.S.C. § 1962(d))**

627. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

628. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

629. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity.

**COUNT VI:
NEGLIGENCE**

630. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

631. Defendants had an obligation to use reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to Tennessee and Shelby County, and the

injuries alleged in this Complaint from the breach of that duty were foreseeable, and in fact were foreseen, by Defendants. *See City of Everett v. Purdue Pharma L.P. et al.*, No. C17-209RSM, 2017 WL 4236062 at *4, 6-7 (W.D. Wash. Sept. 25, 2017) (sustaining a negligence claim by city against Purdue for damages caused by the opioid crisis).

632. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

633. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Producer Defendants.

634. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

635. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

636. Distributor Defendants breached their duties to exercise due care in the business

of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

637. Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Tennessee and Shelby County and destinations from which they knew opioids were likely to be diverted into Tennessee and Shelby County, in addition to other misrepresentations alleged and incorporated herein.

638. Producer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

639. The Producer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

640. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

641. Defendants’ breaches were intentional and unlawful, and Defendants’ conduct was willful, wanton, malicious, reckless, oppressive, and fraudulent.

642. The causal connection between Defendants’ breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

643. Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and proximately resulted in the damages sought herein.

644. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

645. As a direct and proximate result of Defendants' breaches of duties, Plaintiff has been harmed and damaged.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court:

- A. Enter judgment against Defendants jointly and severally and in favor of Plaintiff;
- B. Award damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- C. Award actual and triple the actual damages Shelby County sustained as a result of the Defendants' RICO violations;
- D. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;
- E. Enter an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including over-promotion and over-saturation of opioids in and around Shelby County;
- F. Enter an order requiring Defendants to establish an "abatement fund" for the

purpose of abating the opioid nuisances;

G. Award Plaintiff the costs of this lawsuit, including reasonable attorneys' fees and expenses as provided by law;

H. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Shelby County demands a jury trial on all issues so triable.

Filed on this the 1st day of August, 2018

Respectfully submitted,

/s/ J. Gerard Stranch, IV
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